App	Product	NME ingredients	unii	Therapeutic Class	Molecule Type	App Type	IND date	IND date note	indDateComment	IND date ref	App submitted date	App submitted date ref	App approval date	App ref	Days in clinical development	Days in review	First	Orphan	Fast track	Break-through	Priority	Accelerated	Non-first cycle	Black box	Diagnostic imaging	Animal rule
213006	Gemtesa	vibegron	M5TSE03W5U	Endocrinology	small molecule	NDA	1/29/2010		January 29, 2010. The original Sponsor, Merck, submitted the opening Investigational New Drug (IND), IND 106410 in January 2010. January 29, 2010	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213006Orig1s000MultidisciplineR.pdf	12/26/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/23/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213006	3981	363										
761172	Ebanga	ansuvimab	TG8BQ19NG2	Antiviral	antibody	BLA	1/25/2018		IND 138090 was submitted on January 25, 2018 by the National Institute of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID) Vaccine Research Center (VRC), to study VRC-EBOMAB092-00-AB (mAb114) referred to as ansuvimab-zykl, for the indication of treatment of Zaire ebolavirus (EBOV) infection. Safety was determined in a Phase 1 healthy human subjects study (NIH-18-I-0069) conducted in the United States https://clinicaltrials.gov/ct2/show/NCT03478891 Other Study ID Numbers: 18-I-0069 Actual Study Start Date : May 16, 2018	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/761172Orig1s000IntegrateR.pdf	5/29/2020	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/21/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761172	1061	206		1		1	1					
214621	Orgovyx	relugolix	P76B05O5V6	Oncology	small molecule	NDA	12/1/2007		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/214621Orig1s000MultidisciplineR.pdf Original sponsorship of IND 118,736 (for the treatment of advanced prostate cancer) was transferred from Takeda to Myovant on 03 May 2016 for continued development. Relugolix is not currently marketed in the US. Relugolix monotherapy (40 mg) has been commercialized in Japan since 2019 for treatment of symptoms associated with uterine fibroids under the brand name Relumina™. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/214621Orig1s000ChemR.pdf IND 118,736 for the proposed indication of GnRH antagonist prostate cancer on 12/11/2013 https://adisinsight.springer.com/drugs/800028257 Takeda reported in November 2011 that it was conducting phase I development of relugolix in the treatment of prostate cancer. https://www.sec.gov/Archives/edgar/data/1679082/000095012316018298/filename1.htm TAK-385_101: A Double-Blind, Randomized, Placebo-Controlled, Sequential-Panel, Ascending Single- and Multiple-Dose Study to Evaluate the Effect of TAK-385 on Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics in Healthy Premenopausal Women United States (2007-2008) In 2007, Takeda submitted an IND for relugolix (also known as TAK-385) to the FDA for the treatment of endometriosis and, in May 2016, Takeda transferred this IND to us.	https://www.sec.gov/Archives/edgar/data/1679082/000095012316018298/filename1.htm	4/20/2020	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/18/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=214621	4766	242					1					
761150	Margenza	margetuximab	K91R84KEW	Oncology	antibody	BLA	8/1/2010		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/761150Orig1s000MultidisciplineR.pdf Margetuximab has been developed under IND 107768 for treatment of HER2+ carcinomas since 2010. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6246722/ A total of 66 patients (34 Regimen A and 32 Regimen B) were enrolled and treated between August 2010 and July 2015 at 3 study sites.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/761150Orig1s000MultidisciplineR.pdf	12/18/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/16/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761150	3790	364			1					1		
213189	Klisyri	tirbanibulin	4V9B48R5SG	Endocrinology	small molecule	NDA	7/31/2014		On June 27, 2014, the Division received correspondence to open IND 122464 for investigational drug KX2-391 ointment topical formulation intended for the treatment of actinic keratosis. Study KX2-001 was considered safe to proceed on July 31, 2014.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213189Orig1s000MultidisciplineR.pdf	12/30/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/14/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213189	2328	350	1									
214094	Orladeyo	berotralstat	KZA0KB1BDQ	Hematology	small molecule	NDA	5/1/2015		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/214094Orig1s000MultidisciplineR.pdf IND 135058, which was opened on June 22, 2017. Prior to opening the IND, the Applicant had multiple ex-US clinical studies (completed and … Study BCX7353-101 (SAD) Phase 1 101 SAD and MAD in healthy subjects https://clinicaltrials.gov/ct2/show/NCT02448264 First-in-Human Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of BCX7353 in Healthy Western and Japanese Volunteers Other Study ID Numbers: BCX7353-101 A Phase 1, Randomized, Double-blind, Placebo-controlled, Dose-ranging Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Single and Multiple Doses of BCX7353 in Healthy Subjects. Study Start Date : May 2015	https://clinicaltrials.gov/ct2/show/NCT02448264	12/3/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/3/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=214094	2043	366	1	1								
212642	gallium Ga 68 PSMA-11	gallium Ga 68 PSMA-11	ZJ0EXR6M10	Oncology	peptide	NDA	8/24/2015		Investigational New Drug (IND) 130649 from UCLA was received May 3, 2016, and IND 127621 from UCSF was received on August 24, 2015.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/212642Orig1s000MultidisciplineR.pdf	9/6/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/1/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212642	1926	452	1								1	
213793	Imcivree	setmelanotide	N7T1SV1FUY	Endocrinology	peptide	NDA	10/12/2011		On 12 October 2011, Rhythm Pharmaceuticals opened IND 112595 to pursue development of RM-493 for treatment of obesity. The following key meetings and …	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213793Orig1s000MultidisciplineR.pdf	3/27/2020	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/25/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213793	3332	243	1	1		1	1					
761171	Danyelza	naxitamab	9K8GNJ2874	Oncology	antibody	BLA	NA	Original IND submission date not provided	Y-mAbs submitted IND 132793 on 05 September 2017 after acquiring the rights to naxitamab from Memorial Sloan Kettering Cancer Center (MSK). MSK had studied naxitamab under IND 112594 since 2012 and under IND (bl (4).	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/761171Orig1s000MultidisciplineR.pdf	3/31/2020	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/25/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761171	NA	239	1		1	1	1		1		
214103	Oslumo	lumasiran	R2T8C352O1	Endocrinology	oligo	NDA	3/8/2016		Application Number: IND 128941. Product Name: lumasiran (ALN-GO1). February 9, 2016 Pre-IND meeting (written responses). Actual Study Start Date: March 8, 2016 https://clinicaltrials.gov/ct2/show/NCT02706886	https://clinicaltrials.gov/ct2/show/NCT02706886	4/3/2020	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/23/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=214103	1721	234	1	1		1	1					
213969	Zokinvy	lonafarnib	ICW153004F	Endocrinology	small molecule	NDA	12/1/1997		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213969Orig1s000RiskR.pdf The clinical benefit of lonafarnib in patients with HGPS was primarily based on the retrospective analysis comparing the survival data from two phase 2 trials (studies 07-01-0007 and 09-06-0298) to those from a natural history cohort. Of note, these two trials were investigator-initiated trials, and the Applicant of this NDA was not involved with the design of these trials. 11/02/2018: Eiger submitted IND 138923 with breakthrough designation request. Eiger submitted an initial IND for lonafarnib for the treatment of HGPS and PL without a clinical protocol on October 15, 2018. Per the Division's recommendation, Eiger withdrew and resubmitted IND 138923 on November 2, 2018, along with an expanded access treatment study protocol EIG-EAP-LNF-001. FDA issued a Study May Proceed letter on November 30, 2018. https://clinicaltrials.gov/ct2/show/NCT00425607 Study Start Date : May 2007 Other Study ID Numbers: 07-01-007 https://theoncologist.onlinelibrary.wiley.com/doi/pdfdirect/10.1634/theoncologist.10-8-565 Lonafarnib The first phase I trial of lonafarnib started in 1997. https://link.springer.com/article/10.1007/s00280-010-1488-5 The study was conducted from December 1997 to April 1999	https://link.springer.com/article/10.1007/s00280-010-1488-5	3/20/2020	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/20/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213969	8390	245	1	1		1	1					
214787	Veklury	remdesivir	3QI637EEHE	Antiviral	small molecule	NDA	7/1/2015		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/214787Orig1s000MedR.pdf An Investigational New Drug application (IND) for RDV [for SARS-CoV-2] was submitted on February 24, 2020 by Gilead Sciences, Inc. Fast track designation for RDV for treatment of coronavirus disease 2019 (COVID-19) was granted on March 26, 2020. In July 2015, Gilead filed an investigational new drug (IND) application and in August 2015 initiated its own Phase 1 studies evaluating the safety and pharmacokinetics of remdesivir in healthy volunteers. https://www.gilead.com/-/media/gilead-corporate/files/pdfs/covid-19/gilead_rdv-development-fact-sheet-2020.pdf	https://www.gilead.com/-/media/gilead-corporate/files/pdfs/covid-19/gilead_rdv-development-fact-sheet-2020.pdf	8/7/2020	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/22/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=214787	1940	76	1		1		1					
761169	Inmazeb	atoltivimab| maftivimab| odesivimab	FJ207Q63VY| KOP9S331M4| UY9LQ8P6HW	Antiviral	antibody	BLA	5/27/2016		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/761169Orig1s000MultidisciplineR.pdf Regeneron Pharmaceuticals initiated the REGN-EB3 development program under the Animal Rule. However, with the occurrence of the Ebola outbreak in the North Kivu province of the Democratic Republic of the Congo (DRC) in 2018, the Applicant was able to obtain randomized, controlled clinical data to support the safety and effectiveness of REGN-EB3 for EBOV infection through a traditional approval pathway. The registrational investigational new drug application (IND) is IND 125507. In the initial proposed label, the Applicant included only data from the phase 1 first-in-human, healthy volunteer study (Study 1528). This was a randomized, double-blind, placebo-controlled, dose escalation … Because REGN-EB3 contains proteins that could induce antibody formation, antidrug antibodies (ADAs) were measured in Study 1528 (NCT02777151). https://clinicaltrials.gov/ct2/show/NCT02777151 Actual Study Start Date : May 27, 2016	https://clinicaltrials.gov/ct2/show/NCT02777151	2/25/2020	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/14/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761169	1601	232	1	1		1	1					
213721	Gavreto	pralsetinib	1WPE73O1WV	Oncology	small molecule	NDA	3/17/2017		The clinical investigation and FDA interactions for pralsetinib for the treatment of RET-fusion (b) (4) positive NSCLC were conducted primarily under IND 143094. Table 3 summarizes the key health authority interactions. IND 143094 was submitted to FDA on 30 August 2019 for the investigation of pralsetinib for the treatment of RET-fusion positive NSCLC. Amendment 1 (dated 09 January 2017) The pralsetinib dose and regimen (400 mg QD) was selected on the basis of a Phase 1/2 study that evaluated the efficacy and safety of pralsetinib (Study BLU-667-1101). https://clinicaltrials.gov/ct2/show/NCT03037385 Other Study ID Numbers: BLU-667-1101 Actual Study Start Date : March 17, 2017 .. https://www.blueprintmedicines.com/wp-content/uploads/2018/12/BLU-667-CORTC-2017-8PM.pdf "BLU-667 Phase 1 Study Initiated and First Patient Enrolled in March 2017"	https://clinicaltrials.gov/ct2/show/NCT03037385	3/23/2020	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/4/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213721	1267	165		1		1	1	1				
213227	Detectnet	copper Cu 64 dotatate	N38S837?KC	Oncology	peptide	NDA	NA	Original IND submission date not provided	A pre-investigational new drug (IND) meeting was held on October 4, 2016 during which the Applicant presented literature findings from Pfeifer et al., 2012, and Pfeifer et al., 2015 (Pfeifer et al. 2012; Pfeifer et al. 2015). IND 131797	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213227Orig1s000MultidisciplineR.pdf	1/3/2020	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/3/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213227	NA	244		1	1		1				1	
761156	Sogroya	somapacitan	8FOJ430U94	Endocrinology	protein	BLA	7/23/2014		On July 23rd, 2014, the Applicant submitted the initial IND 116327 including the phase 3 trial protocol for study NN8640-4054 in AGHD. The study was deemed safe to proceed from a clinical standpoint.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/761156Orig1s000MedR.pdf	8/28/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/28/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761156	2228	366										
213433	Winlevi	clascoterone	XN7MMBXG2M	Endocrinology	small molecule	NDA	1/31/2012		The Applicant developed clascoterone under investigational new drug (IND) application 112137. The IND was opened on January 31, 2012, with a phase 2, multicenter, randomized, doubleblind, vehicle-controlled, dose-escalating study to evaluate the safety and efficacy of cortexolone 17α- propionate (cb-03-01)	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213433Orig1s000AdminCorres.pdf	8/27/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/26/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213433	3130	365	1									
761149	Enspryng	satralizumab	Y818NF020M	Neurology	antibody	BLA	9/19/2013		Original IND: 9/19/13	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/761149Orig1s000MedR.pdf	8/15/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/14/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761149	2521	365	1	1	1	1						
212154	Viltepso	viltolarsen	SXA7YP6EKX	Neurology	oligo	NDA	6/1/2013		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/212154Orig1s000MedR.pdf Viltolarsen is approved in Japan. 20 October 2015 Pre-IND meeting. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/212154Orig1s000ClinPharmR.pdf Phase 1 NCNP/DMT01 (NCT02081625) Japan Completed https://www.pmda.go.jp/files/000237467.pdf In Japan, a clinical study was started as an investigator-initiated trial supported by Health and Labour Sciences Research Grants by the National Center of Neurology and Psychiatry in June 2013. Japanese Phase I investigator-initiated study (CTD 5.3.5.2-1, Study DMT01, June 2013 to September 2014) https://clinicaltrials.gov/ct2/show/NCT02081625 Study Start Date : June 2013	https://clinicaltrials.gov/ct2/show/NCT02081625	12/12/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/12/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212154	2629	244		1	1		1	1				
210730	Olinvyk	oliceridine	MCN8S8TCP0	Neurology	small molecule	NDA	12/22/2011		The IND was submitted on December 22, 2011. February 19, 2016 Grant Breakthrough Therapy Designation. • Trevena initially requested …	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/210730Orig1s000MultidisciplineR.pdf	11/2/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/7/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210730	3151	1009			1			1	1			
213535	Evrysdi	risdiplam	76RS4S2ET1	Neurology	small molecule	NDA	1/7/2016		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213535Orig1s000MedR.pdf IND 128972 for risdiplam was allowed to proceed on November 10, 2016. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213535Orig1s000ClinPharmR.pdf single ascending-dose study … BP29840 https://clinicaltrials.gov/ct2/show/NCT02633709 BP29840 Actual Study Start Date : January 7, 2016 [in the Netherlands]	https://clinicaltrials.gov/ct2/show/NCT02633709	9/24/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/7/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213535	1674	318	1	1		1						
213464	Lampit	nifurtimox	M84I3K7C2O	Other Infectious disease	small molecule	NDA	11/21/2014		Bayer submitted the Investigation New Drug (IND) 103901, to FDA on November 21, 2014, for nifurtimox tablets for the treatment of Chagas' disease (American Trypanosomiasis) caused by Trypanosoma cruzi in pediatric populations.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213464Orig1s000MultidisciplineR.pdf	12/6/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/6/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213464	2085	244		1		1	1					
761158	Blenrep	belantamab mafodotin	DB1041CXDG	Oncology	antibody	BLA	1/31/2014		The clinical trials included in this application were conducted under IND 119333, which was opened in the US on January 31, 2014 for the treatment of patients with multiple myeloma.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/761158Orig1s000MultidisciplineR.pdf	12/5/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/5/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761158	2378	244	1	1		1	1	1		1		
761163	Monjuvi	tafasitamab	QQA09MLH692	Oncology	antibody	BLA	1/29/2010		29 Jan 2010 Original IND submitted by prior sponsor Xencor, Inc. 21 Sep 2012 IND 114856 submitted	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/761163Orig1s000MultidisciplineR.pdf	12/30/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/31/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761163	3836	214	1	1	1	1	1	1				
206966	Xeglyze	abametapir	6UO390AMFB	Other Infectious disease	small molecule	NDA	12/20/2007		In December 2007, IND 77510 was opened for abametapir lotion for the treatment of head lice infestation. Xeglyze was developed under the IND 77510, which was submitted on December 20, 2007.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/206966Orig1s000MedR.pdf	9/14/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/24/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206966	4600	1775	1					1				
212576	Inqovi	cedazuridine	39S23Q1EW	Oncology	small molecule	NDA	12/18/2013		18 December 2013 Original IND 116145 submission (Phase 1-2 Study ASTX727-01) IND for ASTX727 was opened in the US 21 Feb 2014, for treatment of MDS and CMML	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/212576Orig1s000MultidisciplineR.pdf	12/11/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/7/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212576	2393	209		1			1					
212295	Byfavo	remimazolam	7V4ABU16MB	Neurology	small molecule	NDA	11/10/2008		IND 102486 opened / June 22, 2008 Phase 1 single ascending dose study allowed to proceed on Nov. 10, 2008.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/212295Orig1s000MedR.pdf	4/5/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/2/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212295	4252	454							1			
212950	Rukobia	fostemsavir	97Q273H4L	Antiviral	small molecule	NDA	11/8/2005		November 8, 2005. IND 73916 BMS-663068 was submitted in	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/212950Orig1s000MultidisciplineR.pdf	12/4/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/2/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212950	5350	211	1		1	1	1					
213687	Dojolvi	triheptanoin	2PG07CFW5K	Endocrinology	small molecule	NDA	7/23/2013		IND 117053 was opened July 23, 2013 with the protocol for study 201, a phase 2 openlabel single arm study in n=29 patients	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213687Orig1s000N2NameR.pdf	7/31/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/30/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213687	2534	335		1	1							
213702	Zepzelca	lurbinectedin	2CN60TN6Z5	Oncology	small molecule	NDA	10/9/2015		On October 9, 2015, Pharma Mar submitted IND 127944 to the Division of Oncology. Products 2 (DOP2). This IND contained a new clinical …	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213702Orig1s000AdminCorres.pdf	12/16/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/15/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213702	1711	182		1				1	1			

App	Product	NME ingredients	unii	Therapeutic Class	Molecule Type	App Type	IND date	IND date note	indDateComment	IND date ref	App submitted date	App submitted date ref	App approval date	App ref	Days in clinical development	Days in review	First	Orphan	Fast track	Break-through	Priority	Acceler-ated	Non-first cycle	Black box	Diagnostic imaging	Animal rule
761142	Uplizna	inebilizumab	74T7185BMM	Neurology	antibody	BLA	2/27/2014		Pre-IND meeting: 5/ 20/ 13 May Proceed: 2/ 27 / 14	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/761142Orig1s000MedR.pdf	6/11/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/11/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761142	2296	366	1	1		1						
212123	Tauvid	flortaucipir F 18	T1JP1KYU9O	Neurology	small molecule	NDA	10/30/2013		(IND) 119863; the IND was allowed to proceed on October 30, 2013, to study FTP to estimate tau pathology in	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/212123Orig1s000IntegratedR.pdf	9/30/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/28/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212123	2402	241	1				1				1	
213036	artesunate	artesunate	60W3249T9M	Other Infectious disease	small molecule	NDA	NA	Ex-US clinical development predates IND	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213036Orig1s000MultidisciplineR.pdf Following the publication of SEAQUAMAT and AQUAMAT, in 2010, the WHO recommended parenteral artesunate as preferred treatment for severe malaria. The Office of the Surgeon General, Department of the Army (US Army), submitted an IND for (b) (4) the development of IV artesunate for the treatment of severe malaria. Study 1128 Phase 1 single dose, dose escalation in healthy volunteers Patient level datasets, CRF, CSR https://clinicaltrials.gov/ct2/show/NCT00292929 Unique Protocol ID: WRAIR 1128 Record Verification: March 2006 Overall Status: Recruiting [However, considerable international work precedes this, e.g. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(05)67176-0/fulltext]	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213036Orig1s000MultidisciplineR.pdf	9/26/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/26/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213036	NA	243		1	1	1	1					
212155	Cerianna	fluoroestradiol F 18	T32277KB09	Oncology	small molecule	NDA	NA	Ex-US clinical development predates IND	The Applicant received authorization to market FES in France on July 21, 2016, under the tradename Estrotep (Parikh et al. 2017).	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/212155Orig1s000MultidisciplineR.pdf	2/27/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/20/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212155	NA	448									1	
213973	Qinlock	ripretinib	9XW757O13D	Oncology	small molecule	NDA	8/11/2015		The Investigational New Drug (IND) application was opened for IND 125279 on August 11, 2015.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213973Orig1s000MultidisciplineR.pdf	12/13/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/15/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213973	1739	154		1	1	1	1					
213246	Retevmo	selpercatinib	CEGM9YBNGD	Oncology	small molecule	NDA	3/2/2017		In May 2017, the Sponsor initiated the clinical development program for selpercatinib under IND 133193 (submitted 02 March 2017). In September 2019, the pediatric study (LOXO-RET18036) was initiated under IND 142299 (submitted on 13 December 2018). 31 March 2017 – IND 133193 submitted to the Division of Oncology Products 2	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213246Orig1s000MultidisciplineR.pdf	12/4/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/8/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213246	1163	156		1		1	1	1				
213591	Tabrecta	capmatinib	TY34L4F9OZ	Oncology	small molecule	NDA	11/9/2012		Novartis submitted IND 116,691 on 09-Nov-2012 to FDA to support the investigation of capmatinib in MET-dependent advanced solid tumors.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213591Orig1s000MultidisciplineR.pdf	12/10/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/6/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213591	2735	148		1		1	1	1				
212489	Ongentys	opicapone	Y5929UIJ5N	Neurology	small molecule	NDA	4/30/2009		Opicapone has been approved in the European Union since June 2016 under the name Ongentys. The clinical trials development program was performed exclusively outside the US. 2009 April 30 • Development International Birth Date 2011 June 27 • IND 104380 is allowed to proceed.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/212489Orig1s000MedR.pdf	4/26/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/24/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212489	4012	364										
761115	Trodelvy	sacituzumab govitecan	M9BYU8XDQ6	Oncology	antibody	BLA	6/1/2012		June 1, 2012: Original IND submission to evaluate of sacituzumab (IMMU-132, hRS7-SN38) in patients with advanced epithelial malignancies (IND 115621).	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/761115Orig1s000MultidisciplineR.pdf	5/18/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/22/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761115	2882	705	1		1	1	1	1	1	1		
213411	Tukysa	tucatinib	234248D0HH	Oncology	small molecule	NDA	7/24/2007		The development of tucatinib in subjects with advanced cancer was initiated by Array BioPharma, Inc. under investigational new drug (IND) 78304 in 2007. 24-Jul-2007 Study May Proceed (IND 078304) Protocol ARRAY-380-101- First in human study	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213411Orig1s000MultidisciplineR.pdf	12/20/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/17/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213411	4651	119		1	1	1	1					
213736	Pemazyre	pemigatinib	Y6BX7BL23K	Oncology	small molecule	NDA	10/27/2014		October 27, 2014 The initial IND for INCB054828 (IND 124358) was submitted, containing the clinical protocol for Study INCB 54828-101	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213736Orig1s000MultidisciplineR.pdf	9/30/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/17/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213736	1999	200		1		1	1	1				
213756	Koselugo	selumetinib	6UH91I579U	Neurology	small molecule	NDA	3/8/2007		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213756Orig1s000MultidisciplineR.pdf September 8, 2014 A pre-IND meeting was held among the FDA, the NCI, and the Applicant to discuss the development program for selumetinib for pediatric patients with inoperable NF1-related PN based on preliminary clinical results from the ongoing NCI-sponsored Study 11-C-0161 (CTEP#8799; SPRINT): "A phase 1 study of the mitogen activated protein kinase (MEK) 1 inhibitor AZD6244 hydrogen sulfate (selumetinib sulfate) in children with NF1 and inoperable (b) (4) plexiform neurofibromas." This study was conducted under IND [proprietary]. NCI, with the support of the Applicant, proposed to amend the ongoing SPRINT study with the incorporation of a single arm expansion cohort to further investigate the safety and effectiveness of selumetinib in pediatric patients with NF1-related PN. Listing of Clinical Trials Relevant to this NDA. D1532C00005 (00463814) Phase I, open label https://clinicaltrials.gov/ct2/show/NCT00463814 Other Study ID Numbers: D1532C00005 Actual Study Start Date : March 8, 2007	https://clinicaltrials.gov/ct2/show/NCT00463814	9/13/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/10/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213756	4782	210	1	1		1	1					
209899	Zeposia	ozanimod	Z80293URPV	Neurology	small molecule	NDA	1/1/2011		The study was conducted between January 2011 and February 2012 under a US investigational new drug application and was approved by the IntegReview Ethical Review Board (Austin, Texas). https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/209899Orig1s000MedR.pdf Ozanimod was originally studied under IND 109159. IRT review for IND 109159 dated 01/29/2014 https://clinicaltrials.gov/ct2/show/NCT01628393 Actual Study Start Date : September 18, 2012	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5516232/	3/25/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/25/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209899	3371	366										
212801	Isturisa	osilodrostat	5YL4IQ1078	Endocrinology	small molecule	NDA	5/30/2013		On May 30, 2013, Novartis submitted IND 117489. The product was at that time referred to as. LCI699 hard gelatin capsule. Acknowledgement ... < <	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/212801Orig1s000StatR.pdf	3/7/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/6/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212801	2472	365	1	1								
761113	Sarclisa	isatuximab	R30772KCU0	Oncology	antibody	BLA	12/29/2009		Safe to Proceed letter on December 29, 2009	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/761113Orig1s000MultidisciplineR.pdf	4/30/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/2/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761113	3716	307		1								
212728	Nurtec ODT	rimegepant	997WVV895X	Neurology	small molecule	NDA	11/18/2010		The investigational new drug (IND) application 109886 was opened on October 22, 2010, for rimegepant for the acute treatment of migraine. At that time, the sponsor of the IND was Bristol-Myers Squibb. The primary safety concern was the potential for hepatotoxicity because of a potential class effect seen with other small molecule CGRP receptor antagonists. The 'May Proceed' notification was issued November 18, 2010	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/212728Orig1s000MedR.pdf	6/27/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/27/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212728	3388	245					1					
209510	Barhemsys	amisulpride	8110R61I4U	Neurology	small molecule	NDA	NA	Ex-US clinical development predates IND	Oral amisulpride (50 mg tabs) is approved/marketed in Europe (for over 30 years) for treatment of schizophrenia at 50 to 1200 mg/day (recommended dose is 400 to 800 mg). IND 114207: Amisulpride, for postoperative nausea and vomiting (PONV); Acacia Pharma, Ltd. APD421 for the prevention and treatment of nausea and vomiting; and APD515 for the treatment of xerostomia (dry mouth). Clinical studies will commence in the final quarter of 2010. APD421 for the prevention and treatment of nausea and vomiting; and APD515 for the treatment of xerostomia (dry mouth). Clinical studies will commence in the final quarter of 2010.https://gildehealthcare.com/news/2011/acacia-pharma-initiates-phase-iia-clinical-trial-with-apd421-for-nausea-vom February 16, 2011 Cambridge, UK – Acacia Pharma, a pharmaceutical company specialising in the development of drugs for cancer supportive care, announces it has initiated a dose-escalating, Phase IIa proof-of-concept study of its product candidate APD421. Phase 2: Study start date 17 Jan 2012 (first patient screened)	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/209510Orig1s000MultidisciplineR.pdf	10/5/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/26/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209510	NA	874							1			
761119	Vyepti	eptinezumab	8202AY8I7H	Neurology	antibody	BLA	12/13/2012		The investigational new drug (IND) application 114647 was opened for ALD403 (eptinezumab) on December 13, 2012	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/761119Orig1s000MedR.pdf	2/21/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/21/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761119	2626	365										
211616	Nexletol	bempedoic acid	1EJ6Z6Q368	Endocrinology	small molecule	NDA	9/23/2009		In the US, the development program for bempedoic acid was carried out under an Investigational New Drug (IND) Application number 106654, under the Division of Metabolic and Endocrine Products (DMEP). The original IND was submitted on 23 September 2009	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/211616Orig1s000IntegratedR.pdf	2/21/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/21/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211616	3803	365	1									
211281	Pizensy	lactitol	L2B0WJF7ZY	Gastroenterology	small molecule	NDA	6/14/2013		June 14, 2013: Investigational new drug (IND) 118906 was submitted to the FDA by Braintree Laboratories Inc (the Applicant).	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/211281Orig1s000MultidisciplineR.pdf	11/21/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/12/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211281	2434	448										
211723	Tazverik	tazemetostat	Q40W93WPE1	Oncology	small molecule	NDA	7/23/2015		On July 23, 2015, IND 124608 was submitted.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/211723Orig1s000MultidisciplineR.pdf	5/23/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/23/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211723	1645	245	1	1			1	1				
761143	Tepezza	teprotumumab	Y64GQ0KC0A	Endocrinology	antibody	BLA	4/1/2006		Teprotumumab infusion was submitted as IND 112952... https://clinicaltrials.gov/ct2/show/NCT00642941 Actual Study Start Date : December 18, 2007. https://ascopubs.org/doi/10.1200/jco.2007.25.18_suppl.3590. https://clinicaltrials.gov/ct2/show/NCT00400361 Study Start Date : April 2006	https://clinicaltrials.gov/ct2/show/NCT00400361	7/8/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/21/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761143	5043	197	1	1	1	1	1					
212608	Ayvakit	avapritinib	513P80B4YJ	Oncology	small molecule	NDA	7/9/2015		On June 9, 2015, IND 125379 was submitted to the Division of Oncology Products 2 (DOP2) containing Protocol BLU-285-1101, a dose-finding study in patients with GIST and other relapsed and refractory solid tumors. The IND was allowed to proceed on July 9, 2015.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/212608Orig1s000MultidisciplineR.pdf	6/14/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/9/2020	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212608	1645	209		1	1	1	1					
211765	Ubrelvy	ubrogepant	AD0O8X2QJR	Neurology	small molecule	NDA	2/3/2012		The investigational new drug (IND) application 113924 was opened for ubrogepant on January 3, 2012, for the acute treatment of migraine. At that time, the sponsor of the IND was Merck. The primary safety concern was the potential for hepatotoxicity because of a potential class effect seen with other small molecule CGRP receptor antagonists. The 'May Proceed' notification was issued February 3, 2012.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211765Orig1s000MedR.pdf	12/26/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/23/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211765	2880	362										
212028	Dayvigo	lemborexant	0K5743G68X	Neurology	small molecule	NDA	7/1/2011		July 2011 - Initial IND 111871 for lemborexant submitted. https://clinicaltrials.gov/ct2/show/NCT01463098 Actual Study Start Date : October 5, 2011	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/212028Orig1s000MultidisciplineR.pdf	12/27/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/20/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212028	3094	358										
209500	Caplyta	lumateperone tosylate	JIE88N006O	Neurology	small molecule	NDA	11/15/2007		The Applicant submitted Investigational New Drug (IND) application 079690 on October 15, 2007. The IND-opening study was an open-label receptor occupancy study; no hold issues were identified and the study was allowed to proceed on November 15, 2007.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/209500Orig1s000MultidisciplineR.pdf	9/27/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/20/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209500	4418	449			1					1		
209569	TissueBlue	brilliant blue G	M1ZRX790SI	Opthamology	small molecule	NDA	NA	Ex-US clinical development predates IND	The company Fluoron GmbH received CE-mark for the product Brilliant Peel as a class IIA medical device in June, 2007 (CE-0535) and the company, DORC (the Sponsor of this application) received CE-mark for its Brilliant Blue G 0.025% Solution (marketed as ILMBlue ®) as a class IIA medical device in August, 2010 (CE-0344). On May 15, 2015, Brilliant Blue G (BBG) was nominated for inclusion on the list of bulk drug substances for use in compounding under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Brilliant Blue G was identified in the nominations as a dye to be used in staining for visualization during ophthalmic procedures. Effective March 21, 2019, Brilliant Blue G was added to the list of bulk drug substances that can be used in compounding under section 503A(b)(1)(A)(i)(III) of the Federal Food, Drug, and Cosmetic Act.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/209569Orig1s000MedR.pdf	4/29/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/20/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209569	NA	235					1				1	
761139	Enhertu	trastuzumab deruxtecan	5384HK7574	Oncology	antibody	BLA	1/27/2016		27 Jan 2016 Original IND 127553 submitted to support initiation of a Phase 1 study (DS8201-A-J101)	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/761139Orig1s000MultidisciplineR.pdf	8/29/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/20/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761139	1423	113			1	1	1	1		1		
761137	Padcev	enfortumab vedotin	DLE8519RWM	Oncology	antibody	BLA	12/28/2012		new IND 116360, was opened (28 Dec 2012) and all subsequent ... The sponsor submitted a new IND (116360) for enfortumab vedotin on.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/761137Orig1s000MultiDisciplineR.pdf	7/15/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/18/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761137	2546	156				1	1	1				
211970	Vyondys 53	golodirsen	033072U4MZ	Neurology	oligo	NDA	11/17/2014		Development of golodirsen proceeded under IND 119982. 11/17/2014 New IND	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211970Orig1s000MedR.pdf	12/19/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/12/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211970	1851	358	1	1	1		1	1	1			
213137	Oxbryta	voxelotor	3ZO554A4Q8	Hematology	small molecule	NDA	10/14/2014		This IND was submitted on October 7, 2014. Orphan drug designation (#15-4997) was granted on December 29, 2015. Drug/Mechanism of ...	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/213137Orig1s000AdminCorres.pdf	6/26/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/25/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213137	1868	152	1	1	1	1	1	1				
212839	Xcopri	cenobamate	P85X70RZWS	Neurology	small molecule	NDA	8/31/2005		12/22/06 Sponsor submitted a new IND 1/26/07 IND was placed on a Full Clinical Hold (seizures in monkeys associated with the administration of YKP3089. In one such study (14-day oral toxicity study in cynomolgus monkeys) this occurred following a second dose of 60 mg/kg.) 6/18/07 IND was placed on a Partial Clinical Hold (dose limited to 250mg) 3/28/08 We removed the Partial Clinical Hold (basis unclear, Clinical Hold Response/Complete correspondence on paper). https://njbiz.com/fda-oks-clinical-trials-for-sks-anxiety-drug/ On August 31, 2005, the US FDA granted IND approval for cenobamate for anxiety ... YKP3089	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/212839Orig1s000MedR.pdf	11/21/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/21/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212839	5195	365	1									
212194	Givlaari	givosiran	ROV204583W	Hematology	oligo	NDA	9/11/2015		On August 13, 2015, IND 126094 was submitted to the Agency to provide for a protocol, Study ALN-AS1-001, entitled, "A Phase 1, Single-ascending Dose, Multiple-ascending Dose, and Multidose Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics Study of Subcutaneously Administered ALN-AS1 in Patients with AIP." The Applicant was notified that they may proceed with their proposed investigation on September 11, 2015.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/212194Orig1s000MultidisciplineR.pdf	6/4/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/20/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212194	1531	169	1	1		1	1					
761128	Adakveo	crizanlizumab	L7451S9126	Hematology	antibody	BLA	2/28/2011		IND 110752 was submitted to FDA on 02/28/11	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/761128Orig1s000MultidisciplineR.pdf	5/16/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/15/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761128	3182	183	1	1		1	1					
213217	Brukinsa	zanubrutinib	AG9MHG098Z	Oncology	small molecule	NDA	8/25/2014		May 12, 2016 EOPI meeting to discuss results of BCB-3111-AU-003 (phase 1 study) and obtain input on registrational pathways for zanubrutinib for MCL, (blf4) . d' t' in 1ca ions IND 125326 Study Title: A Phase I/II, Open-Label, Multiple-Dose, Dose Escalation and Expansion Study to Investigate the Safety and Pharmacokinetics of the BTK Inhibitor BGB-3111 in Patients With B-Cell Lymphoid Malignancies ClinicalTrials.gov identifier: NCT02343120 First Patient Treated: August 25, 2014 https://clinicaltrials.gov/ct2/show/NCT02343120 Actual Study Start Date : November 26, 2014	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/213217Orig1s000MultidisciplineR.pdf	6/27/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/14/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=213217	1907	140		1		1	1	1				

App	Product	NME ingredients	unii	Therapeutic Class	Molecule Type	App Type	IND date	IND date note	indDateComment	IND date ref	App submitted date	App submitted date ref	App approval date	App ref	Days in clinical development	Days in review	First	Orphan	Fast track	Break-through	Priority	Acceler-ated	Non-first cycle	Black box	Diagnostic imaging	Animal rule
209445	Fetroja	cefiderocol	SZ34OMG6E8	Antibacterial	small molecule	NDA	3/22/2013		Cefiderocol was developed under investigational new drug (IND) 116787, which was opened on March 22, 2013.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/209445Orig1s000MultidisciplineR.pdf	12/14/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/14/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209445	2428	335			1		1					
761136	Reblozyl	luspatercept	AQK7UBA1LS	Hematology	antibody	BLA	7/14/2011		On June 14, 2011, IND 112562 was submitted as a multiple ascending dose study of ACE-536 in normal, healthy, post-menopausal women. The study was deemed safe to proceed on July 14, 2011.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/761136Orig1s000MultidisciplineR.pdf	4/4/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/8/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761136	3039	218	1	1	1		1					
212273	Trikafta	elexacaftor	RRN67GMB0V	Respiratory	small molecule	NDA	12/12/2016		ELX and the ELX/TEZ/IVA combination was developed under Investigational New Drug (IND) 132,547, which was opened on December 12, 2016. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/212273Orig1s000MultidisciplineR.pdf 8.2.8.2 Study VX16-445-001 Study 001 was a Phase 1 / 2 study, 6 part study in health volunteers and subjects with CF. Parts A, B, and C evaluated safety and tolerability in healthy volunteers. Part D, E, and F was a randomized, double-blind, parallel-group, multi-part study in 123 CF subjects. https://clinicaltrials.gov/ct2/show/NCT03227471 Actual Study Start Date : January 23, 2017 Other Study ID Numbers: VX16-445-001	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/212273Orig1s000MultidisciplineR.pdf	7/19/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/21/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212273	1043	94		1	1	1	1					
211280	Reyvow	lasmiditan	760I9WM792	Neurology	small molecule	NDA	11/1/2006		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211280Orig1s000MedR.pdf Ownership changed from Eli Lilly and Co to Colucid Pharmaceutics, Inc. in 2005. The investigational new drug application (NDA) 103420 was opened for lasmiditan (also known as COL-144 or LY573144) in July 2011 by the applicant at that time, CoLucid. A "Study May Proceed" letter was issued on September 2011 for a food effect study in health volunteers. The applicant had previously conducted several studies, including bioavailability, pharmacokinetic, and initial tolerability studies, outside the United States (OUS). Nonclinical studies of lasmiditan were reviewed by Dr. Thompson under the IND (Pharmacology/Toxicology IND Review and Evaluation, D. Charles Thompson, Ph.D., dated August 18, 2011. May Proceed Letter (September 12, 2011); https://clinicaltrials.gov/ct2/show/NCT00384774 Actual Study Start Date : November 2006 (2006-10-26)	https://clinicaltrials.gov/ct2/show/NCT00384774	10/11/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/11/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211280	4727	365	1									
200655	Fluorodopa F 18	fluorodopa F-18	2C598205QX	Neurology	small molecule	NDA	NA	Ex-US clinical development predates IND	18F-FDOPA PET was approved in France in 2010 followed by several other countries in the European Union. F18 FDOPA was one of the PET diugs allowed by the FDA in 2000 to be used without an IND or an approved NDA pending the development of the cGMP regulations governing the production of PET drugs. The first New Drug Application (NDA 200655) for 18F-FDOPA was submitted to FDA on October 29, 2009. This submission was based on peer-reviewed publications. FDA refused to file the application on the basis that the submission did not contain adequate information to allow a substantial review. The current applicant has opened an IND 78861 for the use ofF18 FDOPA in Pai·kinsonian patients and submitted an NDA which FDA has at first Refused to File.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/200655Orig1s000MultidisciplineR.pdf	10/22/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/10/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=200655	NA	2544							1		1	
210797	Scenesse	afamelanotide	QW68W3J66U	Dermatology	peptide	NDA	9/1/2006		On December 23, 2008, the Applicant opened IND 103131 with Phase 1b study CUV028 ("Phase 1b study to confirm the pharmacokinetic and melanogenic potential of controlled-release bioresorbable implants of afamelanotide in healthy volunteers"). The first clinical study in the EPP development program was a small single-arm openlabel Phase 2 proof-of-concept study (Study 010). This study was conducted in Europe from September 2006 to February 2007.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/210797Orig1s000MultidisciplineR.pdf	11/8/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/8/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210797	4785	334	1	1	1		1					
761125	Beovu	brolucizumab	XSZ53G39H5	Opthamology	antibody	BLA	4/20/2011		Alcon submitted IND 112023 on 4/20/2011 for ESBA1008. (brolucizumab) for AMD. Sponsorship was formally changed from. Alcon to Novartis ...	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/761125Orig1s000PharmR.pdf	2/7/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/7/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761125	3092	242	1				1					
211527	Aklief	trifarotene	0J8RN2W0HK	Dermatology	small molecule	NDA	2/3/2011		The Applicant developed trifarotene under investigational new drug (IND) application 111091. The IND was opened on February 3, 2011, with ...	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211527Orig1s000MultidisclipineR.pdf	10/4/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/4/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211527	3165	365	1									
211801	Ibsrela	tenapanor	WYD79216A6	Gastroenterology	small molecule	NDA	10/21/2010		Tenapanor (also known as AZD1722 and RDX 5791) is a new molecular entity and is not currently marketed in the U.S. The drug was initially developed for the treatment of IBS-C; investigational new drug (IND) application 108732 was opened by Ardelyx, Inc. on October 21, 2010.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211801Orig1s000MultidisciplineR.pdf	9/12/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/12/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211801	3248	365								1		
22075	Nourianz	istradefylline	2GZ0LIK7T4	Neurology	small molecule	NDA	7/1/1996		Kyowa Hakko Kirin initiated the clinical evaluation of KW-6002 in 1996. https://www.sciencedirect.com/topics/nursing-and-health-professions/istradefylline Istradefylline (KW 6002) entered Phase II trials in the US in 10/99 and completed Phase IIa trials showing good tolerability.	https://www.biospace.com/article/releases/kyowa-hakko-kirin-announces-development-policy-for-anti-parkinson-s-disease-drug-kw-6002-istradefylline-/	4/25/2007	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/27/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022075	8457	4507							1			
210828	Ga 68 DOTATOC	edotreotide gallium Ga-68	Y68179SY2L	Oncology	peptide	NDA	7/2/2001		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/210828Orig1s000MultidisciplineR.pdf The Applicant, University of Iowa Hospitals and Clinics (UIHC)-PET Imaging Center, developed Ga-68-DOTATOC with two investigational new drug (IND) applications, IND 114398 and IND 125673, which were initiated on February 10, 2012 and February 11, 2015, respectively. https://link.springer.com/content/pdf/10.1007/s002590100639.pdf Biokinetics and imaging with the somatostatin receptor PET radioligand 68Ga-DOTATOC: preliminary data. Received 2 July and in revised form 30 July 2001	https://link.springer.com/content/pdf/10.1007/s002590100639.pdf	5/23/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/21/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210828	6624	455		1							1	
211672	Xenleta	lefamulin	21904A5386	Antibacterial	small molecule	NDA	10/17/2009		The Applicant opened two INDs to support the development of lefamulin. The first IND. (#106594) for the IV formulation was submitted in October 2009. The second IND (#125546) for the oral formulation was submitted in January 2015. 10/17/2009: Investigation New Drug (IND) 106594 submission for lefamulin IV formulation was received.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211672Orig1s000%2C%20211673Orig1s000RiskR.pdf	12/19/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/19/2019	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211672Orig1s000%2C%20211673Orig1s000TOC.cfm	3593	243	1		1		1					
212327	Inrebic	fedratinib	6L1XP550I6	Oncology	small molecule	NDA	10/24/2007		The initial IND 078286 for fedratinib was submitted by TargeGen on October 24, 2007, for the treatment of patients with myelofibrosis.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/212327Orig1s000MultidisciplineR.pdf	1/3/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/16/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212327	4314	225	1	1			1					
211675	Rinvoq	upadacitinib	4RA0KN46E0	Rheumatology	small molecule	NDA	7/1/2012		Upadacitinib was studied under IND 114717 which was first opened in July 2012.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211675Orig1s000SumR.pdf	12/18/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/16/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211675	2602	241					1					
212725	Rozlytrek	entrectinib	L5ORF0AN1I	Oncology	small molecule	NDA	2/27/2014		the original IND was submitted on February 27, 2014. The regulatory history prior to submission of NDA 212725 is summarized in Table 2.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/212725Orig1s000%2C%2520212726Orig1s000MultidisciplineR.pdf	12/18/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/15/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212725	1995	240		1		1	1	1				
212862	Pretomanid	pretomanid	2XOI31YC4N	Antibacterial	small molecule	NDA	4/28/2005		On April 28, 2005, IND 69,580 was opened for pretomanid (PA-824), for the treatment of MDR-TB.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/212862Orig1s000MultidisciplineR.pdf	12/14/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/14/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212862	5221	243		1	1		1					
211150	Wakix	pitolisant	4BC83L4PIY	Psychiatry	small molecule	NDA	NA	Ex-US clinical development predates IND	The Applicant conducted the drug development program entirely outside of the United States (largely in Europe, but some South American sites participated in the clinical trials). The Applicant applied for European Medicines Agency (EMA) Marketing Authorization of pitolisant on May 7, 2014 for the treatment of narcolepsy with or without cataplexy. Marketing Authorization was granted on March 31, 2016. In study P02-02 (double-blind, randomized, placebo-controlled single dose study), 36 healthy volunteers received single oral dose of pitolisant (1, 5, 10, 20, 40 or 60 mg) or placebo.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211150Orig1s000SumR.pdf	12/14/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/14/2019	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211150Orig1s000TOC.cfm	NA	243	1	1	1		1					
211810	Turalio	pexidartinib	6783M2LV5X	Oncology	small molecule	NDA	8/19/2009		July 21, 2009: Plexxikon submitted Investigational New Drug (IND) application containing the protocol for Study PLX108-01, a dose-finding study of PLX3397 in patients with refractory solid tumors. The IND was deemed safe to proceed on August 19, 2009; the study was initiated in October 2009.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211810Orig1s000MultidisciplineR.pdf	12/3/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/2/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211810	3635	242		1		1	1			1		
212099	Nubeqa	darolutamide	X05U0N2RCO	Oncology	small molecule	NDA	7/13/2012		IND. 114769. Initial IND was submitted to. DOP1 on 7/13/2012. 2. ... Darolutamide received fast track designation, and was submitted as a.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/212099Orig1s000ChemR.pdf	2/26/2019	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/30/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212099	2573	154			1		1					
212320	Accrufer	ferric maltol	MA10QYF1Z0	Hematology	small molecule	NDA	NA	Ex-US clinical development predates IND	On February 18, 2016, a Centralized Marketing Authorization in the European Union (EU/1/15/1075/001) was granted for ferric maltol 30 mg capsules (Feraccru®) for "the treatment of iron deficiency anemia (IDA) in adults with inflammatory bowel disease (IBD)". Phase III ST10-01-301 The first patient's first visit was on 03 October 2011 and the last patient's last visit for the double-blind treatment period was on 11 October 2013. May 15, 2012 Pre-IND Meeting held to discuss ferric maltol clinical development program	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/212320Orig1s000MultidisciplineR.pdf	9/27/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/25/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212320	NA	301										
212819	Recarbrio	relebactam	Y1MYA2UHFL	Antibacterial	small molecule	NDA	9/13/2010		The investigational new drug application (IND) was submitted on September 13, 2010. Since then, the FDA has had several pre-submission ...	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/212819Orig1s000MultidisciplineR.pdf	11/16/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/16/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212819	3228	242			1		1					
212306	Xpovio	selinexor	31TZ62FO8F	Oncology	small molecule	NDA	6/8/2012		The trials included in this application were conducted under IND 114042, which was opened in the U.S. on June 8, 2012.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/212306Orig1s000MultidisciplineR.pdf	8/6/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/3/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212306	2581	331	1	1	1		1	1				
210557	Vyleesi	bremelanotide	PV2WI7495P	Endocrinology	peptide	NDA	1/27/2001		January 27, 2001. The applicant claims March 13, 2002, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 27, 2001, which was 30 days after FDA receipt of the first IND.	https://www.federalregister.gov/documents/2020/08/20/2020-18240/determination-of-regulatory-review-period-for-purposes-of-patent-extension-vyleesi	3/23/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/21/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210557	6719	455	1									
761121	Polivy	polatuzumab vedotin	KG6VO684Z6	Oncology	antibody	BLA	1/7/2011		The Applicant initially submitted IND 109409 on January 7, 2011. Under IND 109409, polatuzumab vedotin was placed on partial clinical.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/761121Orig1s000MedR.pdf	12/19/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/10/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761121	3076	173	1	1		1	1	1				
212526	Piqray	alpelisib	08W5N2C97Q	Oncology	small molecule	NDA	10/5/2010		Actual Study Start Date : October 5, 2010 https://clinicaltrials.gov/ct2/show/NCT01219699 The 4-week rat and dog toxicology studies were reviewed by the FDA under IND the original IND submitted with BLY719 under IND 119183 dated 12/01/2015 in DARRTS; A total of approximately 560 subjects were to be enrolled. A total of 571 subjects were randomized; 342 subjects were enrolled in the PIK3CA mutant cohort and 231 subjects in the PIK3CA non-mutant cohort. The study was conducted under IND 119183. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/212526Orig1s000MultidisciplineR.pdf	https://clinicaltrials.gov/ct2/show/NCT01219699	12/18/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/24/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212526	3153	157	1				1					
125694	Zolgensma	onasemnogene abeparvovec	MLU3LU3EVV	Neurology	virus	BLA	8/8/2013		Date Milestones. 12/20/2011 PreIND meeting. 8/8/2013 IND submission	https://www.fda.gov/media/127961/download	10/1/2018	https://www.fda.gov/media/127961/download	5/24/2019	https://www.fda.gov/vaccines-blood-biologics/zolgensma	2115	235	1	1	1	1	1					
211996	Vyndaqel	tafamidis meglumine	ZU7CF08A1A	Cardiology	small molecule	NDA	8/19/2005		IND 71,880 was submitted on August 19, 2005 to the Division of CardioRenal Drug Products to support the development of Fx-1006A for the treatment of TTR Familial Amyloid Cardiomyopathy. IND 74,866 was submitted on August 17, 2006 to the Division of Neurology Products to support the development of Fx-1006A for the treatment of TTR Familial Amyloid Polyneuropathy. NDA 202-737 was submitted 2/24/2011 for treatment of TTR Familial Amyloid Polyneuropathy at the clinical dose of 20 mg. A Complete Response was sent 6/15/2012 based on clinical considerations.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211996Orig1s000%2C%20212161Orig1s000PharmR.pdf	11/2/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/3/2019	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211996Orig1s000%2C%20212161Orig1s000TOC.cfm	5005	182	1	1	1	1	1					
761105	Skyrizi	risankizumab	90ZX3Q3FR7	Dermatology	antibody	BLA	2/28/2012		The applicant developed risankizumab injection under IND 113306. On February 28, 2012, the applicant opened the IND.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/761105Orig1s000MultidisciplineR.pdf	4/23/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/23/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761105	2611	365										
212018	Balversa	erdafitinib	890E37NHMV	Oncology	small molecule	NDA	3/27/2013		03/27/2013 (IND 117490 SDN 01) IND 117490 was submitted for JNJ-42756493 (erdafitinib) in patients advanced or refractory solid tumors or lymphoma. The submission included a protocol for an ongoing (Spain and France initiated June 2012), first-in-human, dosefinding, clinical study 42756493EDI1001 (EDI1001) in patients with advanced or refractory solid tumors or lymphoma.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/212018Orig1s000MultidisciplineR.pdf	9/18/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/12/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=212018	2207	206				1	1	1				
761062	Evenity	romosozumab	3VHF2ZD92J	Osteology	antibody	BLA	11/1/2006		The romosozumab IND (100391) was opened in November 2006. For a detailed listing of presubmission regulatory activity, refer to the review of the original BLA submission (signed in DARRTS May 3, 2017). An End of Phase 2 meeting was held in 2011.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/761062Orig1s000MultidisciplineR.pdf	7/19/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/9/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761062	4542	994							1	1		
209884	Mayzent	siponimod	RR6P8L282I	Neurology	small molecule	NDA	9/15/2006		Original IND Submission: September 15, 2006 The initial protocol for IND 076122	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/209884Orig1s000MedR.pdf	7/26/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/26/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209884	4575	243					1					
211230	Sunosi	solriamfetol	939U7C91AI	Neurology	small molecule	NDA	5/1/2009		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211230Orig1Orig2s000MedR.pdf Solriamfetol was developed under IND 107203 (for narcolepsy) and IND 122590 (for OSA). Phase I - May 2009 https://link.springer.com/article/10.1007%2Fs40265-019-01123-y	https://link.springer.com/article/10.1007%2Fs40265-019-01123-y	12/20/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/20/2019	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211230Orig1Orig2s000TOC.cfm	3610	455		1								
211371	Zulresso	brexanolone	S39XZ5QV8Y	Neurology	small molecule	NDA	7/31/2014		June 17, 2014, the Sponsor submitted Investigation New Drug (IND) application 122279. The Division determined that the protocol was safe to proceed and sent the May Proceed letter on July 31, 2014. Brexanolone (to be marketed as Zulresso) is chemically identical to the endogenous human hormone allopregnanolone. It is a new molecular entity not currently marketed anywhere in the world for any indication.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/211371Orig1s000MultidisciplineR.pdf	4/19/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/19/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211371	1692	334	1			1	1			1		
208711	Egaten	triclabendazole	4784C8E03O	Other Infectious disease	small molecule	NDA	NA	Ex-US clinical development predates IND	TCBZ has been routinely used for Fasciola spp infection in veterinary practice since 1983. Since 1986, TCBZ has become the mainstay of treatment worldwide [18]. It is active against adults parasites as well as immature flukes migrating through the liver and is thought to irreversibly damage the tegument of the fluke by tubulin inhibition. Cure rates of 79-83% have been reported with a single dose, and about 93% with two doses [23, 24]. After multiple conversations with FDA, Novartis obtained right of reference to three investigator-initiated trials (IITs) and submitted a right of reference statement. CRFs from the Keiser study [4] were submitted to FDA under PIND on September 18, 2017.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208711Orig1s000MultidisciplineR.pdf	6/14/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/13/2019	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208711Orig1s000TOC.cfm	NA	244	1	1	1		1					
761112	Cablivi	caplacizumab	2R27AB6766	Hematology	antibody	BLA	7/2/2007		Clinical trials initiated Dec 2008. https://www.biospace.com/article/releases/ablynx-announces-2008-full-year-results-/. * Initiated a Phase Ib study in May in patients for ALX-0081, an anti-thrombotic, and reported in December that the primary endpoint had been achieved * Initiated a Phase I study in December for ALX-0681, a subcutaneous delivery form of ALX-0081. https://www.ablynx.com/uploads/press-releases/pressreleasealx-0081phase1_en.pdf 2 July, 2007 — Ablynx today announced positive interim results from the ongoing Phase I study of its lead development programme, ALX-0081	https://www.ablynx.com/uploads/press-releases/pressreleasealx-0081phase1_en.pdf	6/6/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/6/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761112	4237	245	1	1	1		1					

App	Product	NME ingredients	unii	Therapeutic Class	Molecule Type	App Type	IND date	IND date note	indDateComment	IND date ref	App submitted date	App submitted date ref	App approval date	App ref	Days in clinical development	Days in review	First	Orphan	Fast track	Break-through	Priority	Acceler-ated	Non-first cycle	Black box	Diagnostic imaging	Animal rule
761085	Jeuveau	botulinum toxin type A	E211KPY694	Dermatology	protein	BLA	NA	Ex-US clinical development predates IND	DWP-450 was approved by the Korean MDSA for marketing on 29-NOV2013. Evolus Inc. proposed the initial development program for JEUVEAU (DWP-450), a botulinum toxin type A for the treatment of moderate-to-severe glabellar lines, during a Pre-IND meeting on 12-MAR-2014 under IND 121493.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/761085Orig1s000MultiR.pdf	5/15/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/1/2019	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761085	NA	627							1	1		
761116	Elzonris	tagraxofusp	8ZHS5657EH	Oncology	protein	BLA	10/22/2003		October 22, 2003. FDA has verified the applicant's claims that the date the investigational new drug	https://www.federalregister.gov/documents/2020/08/31/2020-19085/determination-of-regulatory-review-period-for-purposes-of-patent-extension-elzonris	6/21/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/21/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761116	5539	183	1	1		1	1			1		
761108	Ultomiris	ravulizumab	C3VX249T6L	Hematology	antibody	BLA	NA	Original IND submission date not provided	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761108Orig1s000MultidisciplineR.pdf IND 128367 [no submission date given] ALXN1210-PNH-103 NCT 02598583 Phase 1b, open-label, uncontrolled, multiple-dose, multicenter, intra- and interpatient dose escalation https://clinicaltrials.gov/ct2/show/NCT02598583 Actual Study Start Date : November 2015 Other Study ID Numbers: ALXN1210-PNH-103. https://ashpublications.org/blood/article/126/23/4777/93314/First-in-Human-Single-Ascending-Dose-Study-Safety [no clinical trial date published]	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761108Orig1s000MultidisciplineR.pdf	6/18/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/21/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761108	NA	186		1			1					
761102	Asparlas	calaspargase pegol	T9FVH03HMZ	Oncology	enzyme	BLA	12/19/2007		11/20/2007 New IND 100594 was allowed to proceed 12/19/2007.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761102Orig1s000MultidisciplineR.pdf	12/22/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/20/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761102	4019	363		1								
210166	Motegrity	prucalopride	0A09IUW5TP	Endocrinology	small molecule	NDA	12/1/1994		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210166Orig1s000MultidisciplineR.pdf 1998: The initial investigational new drug application (IND) 055078 was submitted to the FDA by Johnson and Johnson. • 2000-2004: The IND was placed on a partial hold due to genotoxicity and carcinogenicity concerns and was inactivated on July 30, 2004. • October 15, 2009: EMA authorization of prucalopride (Resolor). Throughout their early clinical development that occurred roughly between 1994 and 2000, plasma concentrations of prucalopride ... https://gut.bmj.com/content/42/4/511.info Effect of a novel prokinetic drug, R093877, on gastrointestinal transit in healthy volunteers Accepted October 9, 1997. https://clinicaltrials.gov/ct2/show/NCT00576511 Study Start Date : December 1994 Other Study ID Numbers: PRU-BEL-6	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210166Orig1s000MultidisciplineR.pdf	12/21/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/14/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210166	8779	358										
208078	Firdapse	amifampridine	RU4S6E2G0J	Rheumatology	small molecule	NDA	1/12/2011		12/14/ 2010 Submission of initial IND 106263 • 1/12/11: IND was placed on Partial Clinical hold for insufficient information to assess risks to human subjects as there was a structural alert for genotoxicity. Applicant was not allowed to enroll patients who do not have a history of neoplasm into any clinical study	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208078Orig1s000MedR.pdf	3/28/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/28/2018	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208078Orig1_toc.cfm	2877	245		1		1	1					
211349	Xospata	gilteritinib	66D92MGC8M	Oncology	small molecule	NDA	6/7/2013		IND 117548 Gilteritinib tablet development. 06/07/2013: Investigation New Drug (IND) 117548 submission was received. 25 Feb 2015: End of phase 1 meeting. 13 Nov 2015: Type B pre-phase 3 meeting. 8 Apr 2016: End of phase 2/pre-phase 3 meeting. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5572576/ The first subject in this study was enrolled on October 15, 2013; the last patient was enrolled on August 27, 2015.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/211349Orig1s000RiskR.pdf	3/29/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/28/2018	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/211349Orig1_toc.cfm	2000	244		1	1		1					
210861	Vitrakvi	larotrectinib	PF9462I9HX	Oncology	small molecule	NDA	2/28/2014		On February 28, 2014, IND 121211 was submitted to the Division of ... The IND contained Protocol LOXO-TRK-14001 entitled “A Phase 1a/1b ...	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210861Orig1s000_211710Orig1s000Admincorres.pdf	3/26/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/26/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210861	1732	245	1	1		1	1	1				
210656	Daurismo	glasdegib	K673DMO5H9	Oncology	small molecule	NDA	8/14/2009		The trials included in this application were conducted under IND 105453, which was submitted on August 14, 2009.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210656Orig1s000MedR.pdf	4/27/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/21/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210656	3386	208		1			1			1		
761107	Gamifant	emapalumab	3S252O2Z4X	Rheumatology	antibody	BLA	9/1/2011		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761107Orig1s000MultidisciplineR.pdf March 10, 2011 Pre-investigational new drug meeting to discuss shelf-life requirements, toxicology package, and overall clinical development program November 16, 2015 Discussion of a registrational path for the treatment of patients with primary HLH Studies to Support Safety NI0501-03 NCT010459562 Phase 1, randomized, placebo controlled, Single dose. https://clinicaltrials.gov/ct2/show/NCT01459562 Study Start Date : September 2011 Other Study ID Numbers: NI-0501-03	https://clinicaltrials.gov/ct2/show/NCT01459562	3/20/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/20/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761107	2637	245	1	1		1	1					
210910	Aemcolo	rifamycin	DU69T8ZZPA	Antibacterial	small molecule	NDA	12/28/2009		Rifamycin delayed-release tablets, an oral formulation of rifamycin sodium, is a new molecular entity (NME) and is not approved for marketing in any country. Parenteral and topical formulations of rifamycin SV have been used in Europe (Bergamini and Fowst 1965, Sensi 1983). Drug development for rifamycin was conducted under IND 104034. 12/28/2009 Submission of IND • Study C2009-0201 protocol	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210910Orig1s000MultidisciplineR.pdf	3/16/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/16/2018	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210910Orig1_toc.cfm	3245	245			1		1					
210598	Yupelri	revefenacin	G2AE2VE07O	Respiratory	small molecule	NDA	12/12/2007		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210598Orig1s000MedR.pdf Revefenacin was studied under IND 119840, opened on February 21, 2014 https://clinicaltrials.gov/ct2/show/NCT00555022 Pulmonary Disease, Chronic Obstructive Actual Study Start Date : December 12, 2007.	https://clinicaltrials.gov/ct2/show/NCT00555022	11/13/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/9/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210598	3985	361										
210868	Lorbrena	loratinib	OSP71S83EU	Oncology	small molecule	NDA	8/15/2013		The original IND was submitted on August 15, 2013 with the protocol entitled, “ Phase 1/2 Study of PF-06463922 (an ALK/ROS1 tyrosine kinase ...	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210868Orig1s000Admincorres.pdf	12/5/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/2/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210868	1905	332		1		1	1	1				
210854	Xofluza	baloxavir marboxil	505CXM6OHG	Antiviral	small molecule	NDA	4/7/2015		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210854Orig1s000MedR.pdf The Applicant submitted a pre-IND for baloxavir marboxil in the third quarter of 2015. ... Applicant opened the U.S. IND on January 12, 2016. Single-ascending Dose Study (Study 1510T0811) https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210854Orig1s000ClinPharmR.pdf Title (Study # 1510T0811) A phase 1, randomized, placebo-controlled, single- and multiple-dose* study of S-033188 in healthy adult. The study was conducted at Medical Corporation Heishinkai OPHAC Hospital (Osaka, Japan) between April 7, 2015 and June 16, 2015.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210854Orig1s000ClinPharmR.pdf	4/24/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/24/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210854	1296	183	1				1					
211651	Talzenna	talazoparib	9QHX048FRV	Oncology	small molecule	NDA	11/12/2010		IND. 108708. Initial IND for talazoparib for the treatment of patients with locally advanced and solid tumors was submitted on December 10, 2010 11/12/2010: Investigation New Drug (IND) 108708 submission was received.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/211651Orig1s000RiskR.pdf	4/6/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/16/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211651	2895	193					1					
761092	Revcovi	elapegademase	9R3D3Y0UHS	Hematology	enzyme	BLA	11/3/2009		The IND was submitted on November 3, 2009. The nonclinical team found the nonclinical data provided adequate safety information for the ... < <	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761092Orig1s000PharmR.pdf	10/24/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/5/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761092	3258	346		1	1		1					
211172	Tegsedi	inotersen	0IEO0F56LV	Neurology	oligo	NDA	11/9/2012		12-Oct-2012 IND113968included Protocol CS2, as well as Special Protocol Assessment and Fast Track Designation Request 09-Nov-2012 IND 113968 can proceed	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/211172Orig1s000MedR.pdf	11/6/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/5/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211172	2156	333	1	1	1		1			1		
209816	Nuzyra	omadacycline	090IP5RV8F	Antibacterial	small molecule	NDA	6/1/2005		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/209816Orig1s000,209817Orig1s000MultidisciplineR.pdf The phase 3 clinical development of omadacycline was initiated in 2008. IND 73431 IND 75928 The following safety pharmacology studies (with one noted exception) were reviewed in the original IND 75928 by Drs. Wendy Schmidt and Theresa Allio. This randomized, controlled, evaluator-blinded phase 2 study compared omadacycline and linezolid for the treatment of complicated skin and skin structure infections (cSSSI). Patients were enrolled between July 2007 and January 2008 at 11 sites in the United States. https://link.springer.com/article/10.1007%2Fs40265-018-1015-2 Phase I trials initiated June 2005.	https://link.springer.com/article/10.1007%2Fs40265-018-1015-2	2/2/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/2/2018	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/209816Orig1s000%2C209817Orig1s000TOC.cfm	4871	242			1		1					
209521	Seysara	sarecycline	94O110CX2E	Antibacterial	small molecule	NDA	NA	Original IND submission date not provided	Investigational New Drug Application (IND) 107645. On September 6, 2011, the sponsor requested a Type B guidance meeting. The briefing package included a phase 2 clinical protocol (PR-10411.0) evaluating 3 doses of study drug WC3035 (3.0 mg/kg/day, 1.5 mg/kg/day, and 0.75 mg/kg/day). · Advice/Information Request – June 22, 2011 · Advice/Information Request – October 18, 2010 · Advice/Information Request – August 31, 2010 PR01010 Single-center, randomized, double blind, placebo-controlled, single ascending-dose study. [initial clinical study, unknown date]	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/209521Orig1s000MultidisciplineR.pdf	10/20/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/1/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209521	NA	346										
761097	Libtayo	cemiplimab	6QVL057INT	Oncology	antibody	BLA	12/22/2014		The initial IND (IND 123950) for REGN2810 was submitted to the Division of Oncology Products 1 (DOP 1) on. December 22, 2014. The IND ...	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761097Orig1s000OtherR.pdf	2/28/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/28/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761097	1376	212				1	1					
761063	Emgality	galcanezumab	55KHL3P693	Neurology	antibody	BLA	3/4/2011		March 4, 2011 Initial IND 111,295 Galcanezumab (LY2951742) for Migraine Prophylaxis submitted	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761063Orig1s000MedR.pdf	9/27/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/27/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761063	2764	365										
211288	Vizimpro	dacomitinib	5092U85G58	Oncology	small molecule	NDA	7/14/2005		July 14, 2005 IND 072775 was submitted for first-in-human study	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/211288Orig1s000MultidisciplineR.pdf	1/31/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/27/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211288	4823	239		1			1					
211155	Copiktra	duvelisib	610V23S0JI	Oncology	small molecule	NDA	8/18/2011		18 August 2011 IND 112486 was activated and opened in the United States	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/211155Orig1Orig2s000MultidisciplineR.pdf	2/5/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/24/2018	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/211155Orig1Orig2s000TOC.cfm	2594	231		1	1		1	1		1		
761089	Ajovy	fremanezumab	PF8K38CG54	Neurology	antibody	BLA	10/27/2009		Fremanezumab (TEV-48125 [formerly LBR-101, PF-04427429, and RN307]) has never been marketed in the U.S. or outside the U.S. Pfizer Inc. filed IND 106,533 on October 27, 2009.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761089Orig1s000MedR.pdf	10/16/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/14/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761089	3244	333					1					
761104	Lumoxiti	moxetumomab pasudotox	2NDX4B6N8F	Oncology	antibody	BLA	11/17/2006		November 17, 2006. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 17, 2006.	https://www.federalregister.gov/documents/2020/09/01/2020-19214/determination-of-regulatory-review-period-for-purposes-of-patent-extension-lumoxiti	1/29/2018	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/13/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761104	4318	227	1	1	1		1			1		
210806	Pifeltro	doravirine	913P6LK81M	Antiviral	small molecule	NDA	8/11/2011		August 11, 2011: IND 112796 for DOR was submitted in the US for the treatment of HIV-1 infection.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210806Orig1s000%2C%20210807Orig1s000MultidisciplineR.pdf	10/23/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/30/2018	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210806Orig1s000%2C210807Orig1s000TOC.cfm	2576	311										
211109	Xerava	eravacycline	07896928ZC	Antibacterial	small molecule	NDA	8/20/2009		Eravacycline injection formulation has been studied under IND 104839 which was opened. August 20, 2009. The following is a summary of the ...	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/211109Orig1s000MultidisciplineR.pdf	12/28/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/27/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211109	3294	242			1		1					
761090	Takhzyro	lanadelumab	2372V1TKXK	Endocrinology	antibody	BLA	7/25/2013		July 25, 2013. The applicant claims August 2, 2013, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 25, 2013, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2020/09/14/2020-20104/determination-of-regulatory-review-period-for-purposes-of-patent-extension-takhzyro	12/26/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/23/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761090	1855	240		1	1	1	1					
761094	Oxervate	cenegermin	B6E7K36KT8	Opthamology	protein	BLA	8/1/2014		August 1, 2014. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 1, 2014.	https://www.federalregister.gov/documents/2020/08/20/2020-18239/determination-of-regulatory-review-period-for-purposes-of-patent-extension-oxervate	12/22/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/22/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761094	1482	243	1	1	1	1	1					
206709	Diacomit	stiripentol	R02XOT8V8I	Neurology	small molecule	NDA	NA	Ex-US clinical development predates IND	Stiripentol has been developed by BIOCODEX outside the US. All the studies in this application were not performed under an IND. https://pubmed.ncbi.nlm.nih.gov/6662977/ First published: November-December 1983	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/206709Orig1s000%2C207223Orig1s000MedR.pdf	12/20/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/20/2018	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/206709Orig1s000%2C207223Orig1s000TOC.cfm	NA	243		1			1					
210922	Onpattro	patisiran	50FKX8CB2Y	Neurology	oligo	NDA	3/1/2012		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210922Orig1s000Admincorres.pdf IND 117395 was submitted on April 29, 2013, along with a request for Breakthrough Therapy. Designation. On May, 29, 2013, the sponsor was ... https://clinicaltrials.gov/ct2/show/NCT01559077 Study Start Date : March 2012	https://clinicaltrials.gov/ct2/show/NCT01559077	12/11/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/10/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210922	2353	242	1	1	1	1	1					
209627	Annovera	segesterone acetate	9AMX4Q13CC	Gynecology	small molecule	NDA	7/13/1997		The application for this CVS was opened in July 13, 1997 under IND 049980.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/209627Orig1s000MultidisciplineR.pdf	8/17/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/10/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209627	7698	358										
208623	Galafold	migalastat	C4XNY919FW	Neurology	small molecule	NDA	7/25/2004		AT1001 (migalastat) was studied under IND 068456 which was opened in the United States in 2004 for the indication of FD. February 3, 2004 Pre-IND meeting. 25 July 2004 to 27 November 2004 SAD Study: FAB-CL-101. This was the first-in man, single-center, phase I, randomized, double-blind, single-dose, placebocontrolled, ascending dose study to evaluate the safety, tolerability and pharmacokinetics of AT1001.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208623Orig1s000MultidisciplineR.pdf	12/13/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/10/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208623	5129	240	1	1	1		1	1				
761051	Poteligeo	mogamulizumab	YI437801BE	Oncology	antibody	BLA	12/4/2008		December 4, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 4, 2008.	https://www.federalregister.gov/documents/2020/08/31/2020-19036/determination-of-regulatory-review-period-for-purposes-of-patent-extension-poteligeo	10/4/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/8/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761051	3534	308	1	1		1	1					
210923	Mulpleta	lusutrombopag	6LL5JFU42F	Hematology	small molecule	NDA	1/8/2009		IND 10407 was submitted to the Agency on January 8, 2009	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210923Orig1s000MultidisciplineR.pdf	12/26/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/31/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210923	3491	217			1		1					
210589	Omegaven	fish oil triglycerides	XGF7L72M0F	Hepatology	lipid	NDA	NA	Ex-US clinical development predates IND	Omegaven® was first approved in Germany in 1998, and since then is currently marketed in 40 countries worldwide The development program for Omegaven began in 2005-7 with single-patient expanded access compassionate-use INDs submitted by Dr. Mark Puder, followed by intermediate size expanded access INDs with investigator-initiated protocols submitted under IND 73488 (Sponsor: Boston Children's Hospital [BCH]) and IND 102843 (Sponsor: Texas Children's Hospital [TCH]). The final pre-submission development occurred under IND 114141 (Sponsor: Fresenius Kabi [FK]). Research IND 73488 (Sponsor: Mark Puder, MD). February 9, 2006: Type B PIND Meeting. Updated FDA IND 73488 status information, granted Safe-to-Proceed on December 13, 2006.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210589Orig1s000MultidisciplineR.pdf	12/1/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/27/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210589	NA	238		1	1		1					
210450	Orilissa	elagolix sodium	5948VUI423	Gynecology	small molecule	NDA	7/21/2003		The clinical development of elagolix has been conducted under IND 064802, which was opened on July 21, 2013 [typo in FDA review]. IND 64802 was opened by Neurocrine Biosciences Inc. (NBI) in July 2003.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210450Orig1s000MultiD.pdf	8/23/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/23/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210450	5481	334	1				1					

App	Product	NME ingredients	unii	Therapeutic Class	Molecule Type	App Type	IND date	IND date note	indDateComment	IND date ref	App submitted date	App submitted date ref	App approval date	App ref	Days in clinical development	Days in review	First	Orphan	Fast track	Break-through	Priority	Acceler-ated	Non-first cycle	Black box	Diagnostic imaging	Animal rule
211192	Tibsovo	ivosidenib	Q2PCN8MAM6	Oncology	small molecule	NDA	12/20/2013		The trials included in this application were conducted under IND 119341, which was submitted on December 20, 2013.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/211192Orig1s000MultidisciplineR.pdf	12/21/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/20/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211192	1673	211	1	1	1		1					
210795	Krintafel	tafenoquine	262P8GS9L9	Other Infectious disease	small molecule	NDA	5/1/1998		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210795Orig1s000MultidisciplineR.pdf January 30, 2008 IND 101471 opened https://doi.org/10.4269/ajtmh.1998.58.645 First-time-in-humans safety and pharmacokinetics of WR 238605, a new antimalarial. Published Online: May 1998	https://doi.org/10.4269/ajtmh.1998.58.645	11/22/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/20/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210795	7385	240		1		1	1					
208627	TPOXX	tecovirimat	F925RR824R	Antiviral	small molecule	NDA	11/9/2005		An Investigational New Drug application (IND) for tecovirimat was submitted on November 9, 2005 by SIGA Technologies, Inc.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208627Orig1s000MicroR.pdf	12/8/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/13/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208627	4629	217	1	1	1		1					1
210498	Mektovi	binimetinib	181R97MR71	Oncology	small molecule	NDA	8/1/2009		On January 24, 2012, Novartis submitted an IND for the development of binimetinib with encorafenib for treatment of patients with unresectable or metastatic melanoma harboring BRAF V600 mutations. https://clinicaltrials.gov/ct2/show/NCT01469130 A Phase I Study of Oral MEK162 in Japanese Patients With Advanced Solid Tumors Study Start Date : November 2011 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5344293/ A phase 1 dose-escalation and expansion study of binimetinib (MEK162), a potent and selective oral MEK1/2 inhibitor Between August 2009 and May 2012, a total of 93 patients … https://clinicaltrials.gov/ct2/show/NCT00959127	https://clinicaltrials.gov/ct2/show/NCT00959127	6/30/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/27/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210498	3252	362		1								
210496	Braftovi	encorafenib	8L7891MRB6	Oncology	small molecule	NDA	5/12/2011		IND 111003 for encorafenib held by Array Biopharma Inc. One month GLP-compliant oral toxicology studies were conducted in Sprague-Dawley rats and cynomolgus monkeys and reviewed under IND 111003 to support first-in-human dosing. On January 24, 2012, Novartis submitted IND 113850 for the development of binimetinib with encorafenib for treatment of patients with unresectable or metastatic melanoma harboring BRAF V600 mutations. An IND for encorafenib was submitted on April 12, 2011; was received by the Department of Health and Human Services on April 12, 2011; and the assigned IND number is 111003. 15 IND number 111003 became effective on May 12, 2011.	https://downloads.regulations.gov/FDA-2019-E-3064-0003/attachment_1.pdf	6/30/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/27/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210496	2603	362		1								
210303	Zemdri	plazomicin	LYO9XZ250J	Antibacterial	small molecule	NDA	11/30/2001		Application Number: IND 102563. Product Name: Plazomicin sulfate injection. Indication: Complicated Urinary Tract Infections (cUTI). Sponsor/ …[PDF] CPY Document Title - FDAwww.accessdata.fda.gov › drugsatfda_docs › ndaAug 17, 2005 | IND 63, 735 was submitted November 30, 2001 with protocols for Studies PSE 301 and. PSE 302. The studies were allowed to proceed and 25 …	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210303Orig1s000AdminCorres.pdf	10/25/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/25/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210303	6051	243					1			1		
210365	Epidiolex	cannabidiol	19GBJ60SN5	Neurology	small molecule	NDA	3/31/2014		IND 120055 was submitted to FDA on March 31, 2014 for a study of the safety and efficacy of cannabidiol in the treatment of convulsive seizures associated with Dravet syndrome.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210365Orig1s000MedR.pdf	10/27/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/25/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210365	1547	241		1	1		1					
210867	Moxidectin	moxidectin	NGU5H31YO9	Other Infectious disease	small molecule	NDA	NA	Ex-US clinical development predates IND	Moxidectin has been in development for human use since 1999. Its development was initiated as a collaborative effort between the World Health Organization/Special Program for Research and Training in Tropical Diseases (WHO/TDR) and Wyeth/Pfizer in 1999. Sponsorship of moxidectin was transferred from Pfizer to TDR/WHO in 2011 and subsequently to the current sponsor, MDGH, on October 14, 2014. Pre-investigational new drug (Pre-IND) 126876 was opened in the U. S. on. 07/ 07/2015 for the treatment of onchocerciasis. Moxidectin was first approved for veterinary use in several products in the late 1980s. Subsequently, moxidectin was submitted to the FDA for human use in IND 126876 in 11/2016 followed by the NDA application for moxidectin (NDA 210867) submitted in 10/2017. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210867Orig1s000OtherR.pdf Study 3110A1-100-EU: This was a first in human study in healthy volunteers which tested single doses of moxidectin (or placebo) up to 36 mg. https://accp1.onlinelibrary.wiley.com/doi/pdf/10.1177/0091270003257456 First in human study, no trial date provided	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210867Orig1s000MedR.pdf	10/13/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/13/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210867	NA	243		1			1					
207924	Olumiant	baricitinib	ISP4442I3Y	Rheumatology	small molecule	NDA	6/5/2008		May 6, 2008- initial investigational new drug submission An investigational new drug (IND) application for baricitinib was submitted by the Applicant. After a 30 day safety review, it was determined that the Applicant may proceed with the proposed clinical investigation under IND 102204 on June 5, 2008	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/207924Orig1s000MedR.pdf	1/15/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/31/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207924	3647	867							1	1		
761079	Palynziq	pegvaliase	N6UAH27EUV	Endocrinology	enzyme	BLA	12/27/2007		December 27, 2007. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 27, 2007.	https://www.federalregister.gov/documents/2019/12/06/2019-26327/determination-of-regulatory-review-period-for-purposes-of-patent-extension-palynziq	6/30/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/24/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761079	3801	328	1	1	1		1					
210238	Doptelet	avatrombopag	3H8GSZ4SQL	Hematology	small molecule	NDA	NA	Original IND submission date not provided	December 7, 2012: End of Phase 2 meeting. Note: NDA 210238 was developed under IND 76680 for avatrombopag, but there were 2 previous INDs that contained data, e.g. a thorough QT study, https://clinicaltrials.gov/ct2/show/NCT00441090 Study Start: December 2006 and https://ashpublications.org/blood/article/108/11/477/129633/Single-and-Multiple-Oral-Doses-of-AKR-501-YM477 from at least 2006.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210238Orig1s000MultidisciplineR.pdf	9/21/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/21/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210238	NA	242					1					
207078	Lokelma	sodium zirconium cyclosilicate	D652ZWF066	Endocrinology	polymer	NDA	12/1/2010		In December 2010, the sponsor submitted IND 108951. An IND to develop ZS as a treatment for hyperkalemia was submitted in December 2010. The IND (108951) was initially placed on clinical hold because of adverse kidney/bladder findings in the nonclinical program, an issue that was adequately resolved via changes to the formulation (see Section 4 for further discussion).	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/207078Orig1s000MedR.pdf	5/26/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/18/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207078	2725	1088							1			
761077	Aimovig	erenumab	I5I8VB78VT	Neurology	antibody	BLA	10/16/2012		October 16, 2012. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 16, 2012.	https://www.federalregister.gov/documents/2019/12/03/2019-26081/determination-of-regulatory-review-period-for-purposes-of-patent-extension-aimovig	5/17/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/17/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761077	2039	365	1									
209229	Lucemyra	lofexidine hydrochloride	V47G1SDI1B	Endocrinology	small molecule	NDA	NA	Ex-US clinical development predates IND	In 1995, working closely with NIDA, a US agent for Britannia, submitted IND 47,857. Lofexidine is not approved in the U.S. for any indication. However, the drug has been marketed in the U.K. for the treatment of opioid withdrawal since 1992. Lofexidine was originally investigated as a potential drug to treat hypertension. As such, many of the nonclinical studies in support of earlier human drug development were completed prior to Good Laboratory Practices. The development program for the opioid related indications was initiated under IND 47857 in 1995. In 1975, A. Nattermann & Cie, GmbH succeeded in claiming the composition of lofexidine (Figure 1) using the latter's antihypertensive activity as grounds for nonobviousness of its composition. Lofexidine became available in the former Federal Republic of Germany (FRG) in 1981.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/209229Orig1s000MultidisciplineR.pdf	9/26/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/16/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209229	NA	232			1		1					
125586	Andexxa	andexanet alfa	BI009E452R	Hematology	enzyme	BLA	5/25/2012		May 25, 2012. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 25, 2012.	https://www.federalregister.gov/documents/2019/12/05/2019-26251/determination-of-regulatory-review-period-for-purposes-of-patent-extension-andexxa	12/17/2015	https://www.fda.gov/media/113954/download	5/3/2018	https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/andexxa-coagulation-factor-xa-recombinant-inactivated-zhzo	2169	868	1	1		1	1	1	1			
210493	Akynzeo	fosnetupitant	T672P80L2S	Oncology	small molecule	NDA	9/10/2009		September 10, 2009. FDA has verified the applicant's claim that September 10, 2009, is the date the investigational new drug application (IND) became effective.	https://www.federalregister.gov/documents/2018/02/12/2018-02756/determination-of-regulatory-review-period-for-purposes-of-patent-extension-akynzeo	4/20/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/19/2018	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210493Orig1s000ApprovTOC.cfm	3143	364										
761068	Crysvita	burosumab	G9WJT6RD29	Endocrinology	antibody	BLA	10/3/2008		October 3, 2008. FDA has verified the applicants' claim that the date the investigational new drug	https://www.federalregister.gov/documents/2019/11/29/2019-25821/determination-of-regulatory-review-period-for-purposes-of-patent-extension-crysvita	8/17/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/17/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761068	3483	243	1	1	1	1	1					
209299	Tavalisse	fostamatinib	SQ8A3S5101	Hematology	small molecule	NDA	6/30/2006		June 30, 2006 IND 074939 was opened for R935788 (R788) for ITP. Rigel Pharmaceuticals submitted protocol C-935788-007 e	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/209299Orig1s000MultidisciplineR.pdf	4/17/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/17/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209299	4309	365	1	1								
761067	Ilumya	tildrakizumab	DEW6X41BEK	Rheumatology	antibody	BLA	10/8/2008		October 8, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 8, 2008.	https://www.federalregister.gov/documents/2020/03/03/2020-04362/determination-of-regulatory-review-period-for-purposes-of-patent-extension-ilumya	3/23/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/20/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761067	3450	362										
761065	Trogarzo	ibalizumab	LT369U66CE	Antiviral	antibody	BLA	4/16/2001		Tanox, the original sponsor of IND 9776, submitted an initial IND application for ibalizumab on April 16, 2001.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761065Orig1s000MedR.pdf	5/3/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/6/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761065	6168	307	1	1	1	1	1					
210951	Erleada	apalutamide	4T36H88UA7	Oncology	small molecule	NDA	2/17/2009		IND. 104676. Initial IND was submitted on 2/17/2009. 2. CONSULTS. DISCIPLINE. STATUS RECOMMENDATION DATE REVIEWER.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210951Orig1s000ChemR.pdf	10/10/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/14/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210951	3284	127			1		1					
210491	Symdeko	tezacaftor	8RW88Y506K	Respiratory	small molecule	NDA	4/15/2010		IND 108105 tezacaftor (VX-661) for CF. IND 74633 ivacaftor (VTX-770) for CF. TEZ and the TEZ/IVA combination was developed under IND 108,105, which was opened on 4/15/10.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210491Orig1s000MedR.pdf	6/28/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/12/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210491	2860	229		1	1	1	1					
210251	Biktarvy	bictegravir	8GB79LOJ07	Antiviral	small molecule	NDA	4/28/2014		April 28. 2014: IND 121318, the initial application, was received for bictegravir (GS-9883, BIC), single agent. Based on the results of the Phase 1 trials under this IND, the Sponsor stated their intent is to co-formulate bictegravir as a fixed-dose combination with other ARV's as a complete regimen for the treatment of HIV-1.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210251Orig1s000MultidisciplineR.pdf	6/12/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/7/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210251	1381	240					1			1		
208700	Lutathera	lutetium oxodotreotide LU-177	AE221IM3BB	Oncology	peptide	NDA	1/1/2000		Erasmus Medical Center Clinical Study (MEC 127.545/1993/84-01) An investigator sponsored single arm clinical study 177Lu-DOTA0-Tyr3-Octreotate was conducted at EMC in Rotterdam, The Netherlands, between January 2000 and March 2007. June 14, 2007: A pre-IND meeting was held with BioSynthema Inc. and FDA under IND 77219, to discuss the development program for 177Lu-DOTA0-Tyr3-Octreotate for patients with somatostatin receptor positive NETs. Review of EMC trial, including the CSR, protocol V2.0 dated 18 November 2008. A phase I/II single arm study to evaluate the efficacy of 177LuDOTA0-Tyr3-Octreotate in patients with somatostatin receptor positive tumors; Version Date: 18Nov2008. April 23, 2012: The IND-enabling study (NETTER-1) was submitted to IND 77219.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208700Orig1s000MultidisciplineR.pdf	4/28/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/26/2018	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208700	6600	638	1	1	1		1		1			
209360	Giapreza	angiotensin II	M089EFU921	Endocrinology	peptide	NDA	6/28/2013		June 28, 2013. The applicant claims November 16, 2014, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 28, 2013, which was 30 days after FDA receipt of the first IND. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209360Orig1s000SumR.pdf No human angiotensin II product has ever been marketed as a drug in the US. However, Hypertensin® (NDA 12-791, Ciba-Geigy (now Novartis)), an octapeptide that is identical in sequence to bovine angiotensin II, was approved in the US in 1962 for treatment of shock, but the NDA was withdrawn for reasons unrelated to safety (49 FR 23407-12, May 19, 2009). Bovine angiotensin II differs from the human peptide by one amino acid (valine at position 5 in the bovine peptide instead of isoleucine in the human version). Because of this difference in amino acid sequences between the human and bovine peptides, OPQ considers LJPC-501 to be an NME. There is no foreign marketing history for LJPC-501.	https://www.federalregister.gov/documents/2019/09/05/2019-19110/determination-of-regulatory-review-period-for-purposes-of-patent-extension-giapreza	6/29/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/21/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209360	1637	175	1				1					
205598	Macrilen	macimorelin	8680B21W73	Endocrinology	small molecule	NDA	2/7/2007		The IND for macimorelin was opened in 2007 under a prior sponsor. At that time, the Division agreed that 28 day repeat dose oral toxicity … In brief, the IND for macimorelin acetate was opened on February 7, 2007 by Ardana BioScience with the single pivotal phase III trial (ARD-0705-001) as the IND opening study. Studies comparing macimorelin to the [L-ARG + GHRH] test were originally initiated by Ardana Bioscience, Ltd. (Edinburgh, United Kingdom), but were terminated due to insolvency in the company before the study (Protocol ARD0705-001) was complete. On 04 August 2009 Aeterna Zentaris assumed sponsorship of this application and reactivated US IND 73,196.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/205598Orig1s000MedR.pdf	11/5/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/20/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205598	3969	1506	1	1					1			
209803	Steglatro	ertugliflozin	6C282481IP	Endocrinology	small molecule	NDA	10/16/2009		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209803,209805,209806Orig1s000MedR.pdf IND 106447 (Ertugliflozin) Initial IND Application submitted September 28, 2012. phase I single dose escalation study (P036/1001). https://clinicaltrials.gov/ct2/show/NCT00989079 Actual Study Start Date : October 16, 2009	https://clinicaltrials.gov/ct2/show/NCT00989079	12/19/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/19/2017	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209803%2C209805%2C209806Orig1s000TOC.cfm	2986	365										
125610	Luxturna	voretigene neparvovec	2SPI046IKD	Opthamology	virus	BLA	7/18/2007		July 18, 2007. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 18, 2007.	https://www.federalregister.gov/documents/2019/12/05/2019-26252/determination-of-regulatory-review-period-for-purposes-of-patent-extension-luxturna	5/16/2017	https://www.fda.gov/media/110141/download	12/19/2017	https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/luxturna	3807	217	1	1		1	1					
208254	Rhopressa	netarsudil	W6I5QDT7QI	Opthamology	small molecule	NDA	3/7/2012		IND 113064 nonclinical reviews: Initial IND review – Filed in DARRTS on 3-7-2012. An Open-Label Study Assessing the Ocular and Systemic Safety and Systemic Absorption of AR-13324 Ophthalmic Solution, 0.02% in Healthy Volunteers (Study # AR13324-CS101) was conducted by Aerie Pharmaceuticals, Inc from November 6, 2013 to November 14, 2013 with the final report date – March 7, 2014.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208254Orig1s000PharmR.pdf	2/28/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/18/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208254	2112	293	1									
208945	Xepi	ozenoxacin	V0LH498RFO	Antibacterial	small molecule	NDA	3/26/2010		March 26, 2010. FDA has verified the applicant's claim that the date the investigational new drug application became effective was March 26, 2010.	https://www.federalregister.gov/documents/2020/07/13/2020-15013/determination-of-regulatory-review-period-for-purposes-of-patent-extension-xepi	6/23/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/11/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208945	2817	536							1			
209637	Ozempic	semaglutide	53AXN4NNHX	Endocrinology	peptide	NDA	10/19/2008		October 19, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 19, 2008.	https://www.federalregister.gov/documents/2019/11/29/2019-25850/determination-of-regulatory-review-period-for-purposes-of-patent-extension-ozempic	12/5/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/5/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209637	3334	365								1		

App	Product	NME ingredients	unii	Therapeutic Class	Molecule Type	App Type	IND date	IND date note	indDateComment	IND date ref	App submitted date	App submitted date ref	App approval date	App ref	Days in clinical development	Days in review	First	Orphan	Fast track	Break-through	Priority	Accelerated	Non-first cycle	Black box	Diagnostic imaging	Animal rule
761083	Hemlibra	emicizumab	7NLZE3F6K3	Hematology	antibody	BLA	8/1/2012		7/30/2013: Pre-IND meeting held with Chugai Pharma and CBER, to discuss the plan to initiate the phase 1b study in the US; this study was ultimately completed in Japan without enrolling in the US. 8/7/2015: IND 122954 opened with Study BH29884 (phase 3), breakthrough therapy designation request was submitted at the time of the IND filing. ACE001JP was the first-in-human clinical study. https://clinicaltrials.gov/ProvidedDocs/60/NCT03020160/Prot_000.pdf A total of 64 healthy volunteers were enrolled in Parts A and B from August 2012 to April 2013.	https://clinicaltrials.gov/ProvidedDocs/60/NCT03020160/Prot_000.pdf	6/23/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/16/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761083	1933	146	1	1		1			1		
761047	Mepsevii	vestronidase alfa	7X24062R17	Endocrinology	enzyme	BLA	10/9/2013		The development program for vestronidase alfa was initiated [outside the US]. Clinical investigations of vestronidase alfa in the US commenced under IND 123788, submitted on October 10, 2014. The pivotal phase 3 study (UX003-CL301) was submitted after discussion with the Agency (July 29, 2014). Preceded by 2 INDs: IND 119935 (Expanded Access), IND 123764 (Expanded Access). Study 201 was initiated in Europe prior to submission of IND [] or IND 123788. Three patients with MPS VII were enrolled in three different study centers for this first-in-human study. The date of the original protocol was May 2, 2013. The clinical database search included adverse events from initiation of the first vestronidase alpha treatment in humans, October 9, 2013 (for eIND 119935) = NCT01856218 https://clinicaltrials.gov/ct2/show/NCT01856218 Study Start Date : November 2013	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/761047Orig1s000MedR.pdf	3/16/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/15/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761047	1498	244	1	1	1		1			1	
761070	Fasenra	benralizumab	71492GE1FX	Respiratory	antibody	BLA	7/30/2006		July 30, 2006. The applicant claims July 29, 2006, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 30, 2006, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2020/03/04/2020-04363/determination-of-regulatory-review-period-for-purposes-of-patent-extension-fasenra	11/16/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/14/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761070	4125	363								
209939	Prevymis	letermovir	1H09YSWO1F	Antiviral	small molecule	NDA	3/20/2009		The initial IND for oral letermovir (104706) for the prevention of human CMV disease was opened by AiCuris GmbH & Co. KG on February 18, 2009. After a 30-day safety review, it was determined the Sponsor may proceed with the proposed clinical investigation on March 20, 2009.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209939Orig1s000MedR.pdf	3/8/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/8/2017	https://www.fda.gov/drugsatfda_docs/appletter/2017/209939Orig1s000%2C209940Orig1s000TOC.cfm	3155	245	1	1	1	1	1				
207795	Vyzulta	latanoprostene bunod	I6393O0922	Opthamology	small molecule	NDA	2/20/2007		Pfizer Inc. submitted an IND application for latanoprostene bunod ophthalmic solution (IND 73,435) on February 20, 2007.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/207795Orig1s000MedR.pdf	7/21/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/2/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207795	3908	835						1			
210259	Calquence	acalabrutinib	I4274BELQW	Oncology	small molecule	NDA	11/27/2013		November 27, 2013 IND 118717 was submitted.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/210259Orig1s000MultidisciplineR.pdf	6/13/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/31/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=210259	1434	140		1		1	1	1			
125643	Yescarta	axicabtagene ciloleucel	U2J8T43Y7R	Oncology	virus	BLA	12/3/2008		December 3, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was December 3, 2008.	https://www.federalregister.gov/documents/2019/04/29/2019-08609/determination-of-regulatory-review-period-for-purposes-of-patent-extension-yescarta	3/31/2017	https://www.fda.gov/media/108788/download	10/18/2017	https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/yescarta-axicabtagene-ciloleucel	3241	201	1		1	1					
208716	Verzenio	abemaciclib	60UAB198HK	Oncology	small molecule	NDA	10/16/2009		September 15, 2009: IND 106100 for LY2835219 (abemaciclib) was submitted in the United States for the treatment of advanced cancer to the Division of Oncology Products 1. October 16, 2009: The First in Human dose study, I3Y-MDJP8A was initiated.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208716Orig1s000MultidisciplineR.pdf	5/5/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/28/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208716	2904	146			1	1	1				
209363	Solosec	secnidazole	R3459I699K	Antibacterial	small molecule	NDA	NA	Ex-US clinical development predates IND	December 18, 2013: IND 117811 was submitted for secnidazole. Secnidazole was originally approved in France in 1979 and is commercially available in a number of other countries ...	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209363Orig1s000MedR.pdf	1/17/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/15/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209363	NA	241			1		1				
209936	Aliqopa	copanlisib	WI6V529F29	Oncology	small molecule	NDA	11/19/2009		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209936Orig1s000MultidisciplineR.pdf IND 115916 was activated and opened in the United States. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5035790/ First-in-human phase I study of copanlisib (BAY 80-6946), an intravenous pan-class I phosphatidylinositol 3-kinase inhibitor https://clinicaltrials.gov/ct2/show/NCT00962611 Actual Study Start Date : November 19, 2009	https://clinicaltrials.gov/ct2/show/NCT00962611	3/16/2017	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/14/2017	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209936Orig1s_toc.cfm	2856	182	1	1		1	1				
125646	Kymriah	tisagenlecleucel	Q6C9WHR03O	Oncology	virus	BLA	8/17/2011		https://www.fda.gov/media/107962/download 9/23/2014 IND 16130 submission https://clinicaltrials.gov/ct2/show/NCT01626495 Actual Study Start Date : August 17, 2011	https://clinicaltrials.gov/ct2/show/NCT01626495	2/2/2017	https://www.fda.gov/media/107962/download	8/30/2017	https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/kymriah-tisagenlecleucel	2205	209	1	1		1	1				
209776	Vabomere	vaborbactam	1C7567F8RV	Opthamology	small molecule	NDA	12/3/2012		https://www.federalregister.gov/documents/2019/12/11/2019-26655/determination-of-regulatory-review-period-for-purposes-of-patent-extension-vabomere January 23, 2014. The applicant claims February 6, 2014, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 23, 2014, which was 30 days after FDA receipt of the IND. This is a first marketing application for meropenem-vaborbactam fixed drug combination product. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209776Orig1s000ClinPharmR.pdf Study 402: Single and Multiple Ascending Dose - Vaborbactam Title: A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Ascending Single- and Multiple-Dose Study of the Safety, Tolerability, Pharmacokinetics of Intravenous RPX7009 (Vaborbactam) in Healthy Adult Subjects Information Regarding the Clinical Trial Site and Duration of the Trial: The trial was conducted by Rempex Pharmaceuticals, Inc. from December 03, 2012 to August 16, 2013 with the final report date of June 5, 2014.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209776Orig1s000ClinPharmR.pdf	12/29/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/29/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209776	1730	243		1		1					
209570	benznidazole	benznidazole	YC42NRJJZD	Other Infectious disease	small molecule	NDA	NA	Ex-US clinical development predates IND	Nifurtimox, a nitrofuran derivative, and benznidazole, a nitroimidazole, have been approved in 21 endemic countries in Latin America since the 1960s and 1970s, respectively. Benznidazole and nifurtimox are treatments included in the WHO Essential Medicines List to treat Chagas disease. A Pre-IND (PIND) type B Meeting Request was submitted by CHEMO Research (CHEMO) on June 18, 2013, to discuss a drug development program of benznidazole tablets for the treatment of Chagas disease. PIND number 118976 was assigned on July 9, 2013. The Division of Anti-Infective Products (DAIP) granted a September 17, 2013. Fast Track was not available since and IND was not submitted.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209570Orig1s000MedR.pdf	12/29/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/29/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209570	NA	243		1			1	1			
761040	Besponsa	inotuzumab ozogamicin	P93RUU11P7	Oncology	antibody	BLA	2/16/2003		February 16, 2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on February 16, 2003.	https://www.federalregister.gov/documents/2018/10/22/2018-22958/determination-of-regulatory-review-period-for-purposes-of-patent-extension-besponsa	12/20/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/17/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761040	5296	240	1	1		1	1			1	
209394	Mavyret	glecaprevir/pibrentasvir	K6BUU827QP/2WU922TK3L	Antiviral	small molecule	NDA	11/14/2012		November 14, 2012. FDA has verified the applicant's claim that the date the investigational new drug applications became effective was on November 12, 2012.	https://www.federalregister.gov/documents/2020/01/22/2020-00916/determination-of-regulatory-review-period-for-purposes-of-patent-extension-mavyret	12/14/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/3/2017	https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/209394_toc.cfm	1723	232		1	1	1			1		
209606	Idhifa	enasidenib	3T1554E7AG	Oncology	small molecule	NDA	7/18/2013		07/18/2013: Investigation New Drug (IND) 117631 submission was received.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209606Orig1s000RiskR.pdf	12/30/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/1/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209606	1475	214	1	1	1		1			1	
209195	Vosevi	voxilaprevir	0570F3735I9	Antiviral	small molecule	NDA	3/13/2014		This is the first marketing application for any product containing VOX, a new molecular entity. An Investigational New Drug application (IND) for the SOF/VEL/VOX FDC was submitted on May 22, 2015 by Gilead Sciences, Inc. VOX does not prolong QTc to any clinically relevant extent. Please refer to the QT-IRT review by Huifang Chen for additional details (IND 119926, June 30, 2016). First-in-human study was GS-US-338-1120. The trial was conducted from March 13, 2014 to June 25, 2014, with the final report date of January 5, 2015.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209195Orig1s000ClinPharmR.pdf	12/8/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/18/2017	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209195_toc.cfm	1223	222					1				
208051	Nerlynx	neratinib	9RM7XY23Z5	Oncology	small molecule	NDA	7/31/2003		July 31, 2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was July 31, 2003.	https://www.federalregister.gov/documents/2019/08/30/2019-18816/determination-of-regulatory-review-period-for-purposes-of-patent-extension-nerlynx	7/19/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/17/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208051	5100	363									
761061	Tremfya	guselkumab	08965BA12D	Dermatology	antibody	BLA	5/30/2009		May 30, 2009. The applicant claims April 30, 2009, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 30, 2009, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2018/10/17/2018-22571/determination-of-regulatory-review-period-for-purposes-of-patent-extension-tremfya	11/16/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/13/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761061	2966	239					1				
208383	Bevyxxa	betrixaban	74RWP7WDJ9	Hematology	small molecule	NDA	11/11/2005		November 11, 2005. The applicant claims November 30, 2005, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 11, 2005, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2019/08/30/2019-18788/determination-of-regulatory-review-period-for-purposes-of-patent-extension-bevyxxa	10/24/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/23/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208383	4242	242				1				1	
208610	Baxdela	delafloxacin	6315417YVF	Antibacterial	small molecule	NDA	7/22/2001		July 22, 2001. Melinta Therapeutics, Inc., claims that July 27, 2001, is the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 22, 2001, which was 30 days after FDA receipt of the first IND.	https://www.federalregister.gov/documents/2019/06/11/2019-12299/determination-of-regulatory-review-period-for-purposes-of-patent-extension-baxdela-tablets-inda	10/19/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/19/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208610	5811	243			1		1			1	
761037	Kevzara	sarilumab	NU90V55F8I	Rheumatology	antibody	BLA	11/15/2007		November 15, 2007. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 15, 2007.	https://www.federalregister.gov/documents/2018/11/30/2018-26033/determination-of-regulatory-review-period-for-purposes-of-patent-extension-kevzara	10/30/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/22/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761037	3476	570						1		1	
209176	Radicava	edaravone	5798V6YJRP	Neurology	small molecule	NDA	NA	Ex-US clinical development predates IND	The drug is approved and marketed in several countries as described in Section 3.2. 5/12/2015 – Orphan designation for the treatment of ALS. • 5/13/2015 – IND-126396 received with meeting request (no US trial protocol submission) • 6/16/15 – Pre-IND meeting to discuss the efficacy findings of Phase III study of edaravone for the treatment of ALS	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209176Orig1s000MedR.pdf	6/16/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/5/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209176	NA	323	1	1							
761069	Imfinzi	durvalumab	28X28X9OKV	Oncology	antibody	BLA	7/13/2012		July 13, 2012. FDA has verified the applicant's claim that the date the initial investigational new drug application became effective was on July 13, 2012.	https://www.federalregister.gov/documents/2018/10/19/2018-22806/determination-of-regulatory-review-period-for-purposes-of-patent-extension-imfinzi	10/13/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/1/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761069	1753	200				1	1	1			
207997	Rydapt	midostaurin	ID912S5VON	Oncology	small molecule	NDA	11/19/1998		November 19, 1998. The applicants claim October 19, 1988, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was on November 19, 1998, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2018/12/28/2018-28216/determination-of-regulatory-review-period-for-purposes-of-patent-extension-rydapt	8/29/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/28/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207997	6735	242	1	1	1	1	1				
208772	Alunbrig	brigatinib	HYW8DB273J	Oncology	small molecule	NDA	7/26/2011		July 26, 2011. FDA has verified the applicant's claim that the date the investigational new drug application became effective was July 26, 2011.	https://www.federalregister.gov/documents/2019/06/11/2019-12320/determination-of-regulatory-review-period-for-purposes-of-patent-extension-alunbrig	8/29/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/28/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208772	2103	242		1		1	1	1			
208743	Tymlos	abaloparatide	AV6DI6HY2U	Osteology	peptide	NDA	1/8/2006		January 8, 2006. FDA has verified the applicant's claim that the date the investigational new drug application became effective was January 8, 2006.	https://www.federalregister.gov/documents/2018/10/22/2018-22956/determination-of-regulatory-review-period-for-purposes-of-patent-extension-tymlos	3/30/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/28/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208743	4128	394								1	
761052	Brineura	cerliponase alfa	X8R2D92QP1	Neurology	enzyme	BLA	9/1/2013		https://www.federalregister.gov/documents/2018/10/17/2018-22559/determination-of-regulatory-review-period-for-purposes-of-patent-extension-brineura August 8, 2014. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 8, 2014. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/761052Orig1s000SumR.pdf The IND for cerliponase alfa was opened in July 2014 with an efficacy and safety study (Study 190-201). At the time of the original IND submission this study had been already initiated, and 12 of the 24 patients were already enrolled at sites in Germany and United Kingdom. https://clinicaltrials.gov/ct2/show/NCT01907087 Study Start Date : September 2013	https://clinicaltrials.gov/ct2/show/NCT01907087	5/27/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/27/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761052	1334	335	1	1		1	1				
209241	Ingrezza	valbenazine	54K37P50KH	Neurology	small molecule	NDA	12/21/2009		https://www.federalregister.gov/documents/2020/03/05/2020-04545/determination-of-regulatory-review-period-for-purposes-of-patent-extension-ingrezza August 12, 2011. The applicant claims August 16, 2011, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 12, 2011, which was the first date after receipt of the IND that the investigational studies were allowed to proceed. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209241Orig1s000OtherR.pdf (table 1 from the Study # NBI-98854-0801, PK of ascending doses in Healthy Volunteers) https://www.biospace.com/article/releases/neurocrine-biosciences-inc-advances-vmat2-inhibitor-program-/ The first trial in human subjects, NBI-98854-0801, was a single ascending dose trial in healthy male volunteers conducted in Canada under an approved Clinical Trial Application (CTA) with Health Canada. Published: Dec 21, 2009	https://www.biospace.com/article/releases/neurocrine-biosciences-inc-advances-vmat2-inhibitor-program-/	8/11/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/11/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209241	2668	243		1		1	1				
208082	Austedo	deutetrabenazine	P341GW9N8	Neurology	small molecule	NDA	7/3/2012		July 3, 2012. FDA has verified the applicant's claim that the date the investigational new drug application became effective was July 3, 2012.	https://www.federalregister.gov/documents/2019/05/13/2019-09805/determination-of-regulatory-review-period-for-purposes-of-patent-extension-austedo	5/29/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/3/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208082	1735	675		1					1	1	
761055	Dupixent	dupilumab	420K48F7SG	Dermatology	antibody	BLA	10/10/2009		October 10, 2009. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 10, 2009.	https://www.federalregister.gov/documents/2018/10/17/2018-22566/determination-of-regulatory-review-period-for-purposes-of-patent-extension-dupixent	7/29/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/28/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761055	2726	242	1			1	1				
761053	Ocrevus	ocrelizumab	A105JL62JY	Neurology	antibody	BLA	12/25/2003		December 25, 2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 25, 2003.	https://www.federalregister.gov/documents/2018/10/18/2018-22699/determination-of-regulatory-review-period-for-purposes-of-patent-extension-ocrevus	4/28/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/28/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761053	4842	334	1		1	1	1				

App	Product	NME ingredients	unii	Therapeutic Class	Molecule Type	App Type	IND date	IND date note	indDateComment	IND date ref	App submitted date	App submitted date ref	App approval date	App ref	Days in clinical development	Days in review	First	Orphan	Fast track	Break-through	Priority	Accelerated	Non-first cycle	Black box	Diagnostic imaging	Animal rule
208447	Zejula	niraparib	HMC2H89N3S	Oncology	small molecule	NDA	5/21/2008		May 21, 2008. The applicant claims May 22, 2008, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 21, 2008, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.	https://www.federalregister.gov/documents/2019/02/12/2019-02036/determination-of-regulatory-review-period-for-purposes-of-patent-extension-zejula	10/31/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/27/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208447	3232	147		1	1	1	1						
208854	Symproic	naldemedine	03KSI6WLXH	Gastroenterology	small molecule	NDA	4/28/2010		April 28, 2010. FDA has verified the applicant's claim that the date the investigational new drug application became effective was April 28, 2010.	https://www.federalregister.gov/documents/2019/04/15/2019-07459/determination-of-regulatory-review-period-for-purposes-of-patent-extension-symproic	3/23/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/23/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208854	2521	365											
761049	Bavencio	avelumab	KXG2PI5S5I	Oncology	antibody	BLA	12/13/2012		On November 13, 2012, IND 115747 was submitted to the Division of Oncology Products 2 for avelumab for the treatment of patients with advanced solid tumors. The IND was placed on partial hold on December 12, 2012, for insufficient information provided in the IND to assess whether the safety testing in the master cell bank (MCB) was sufficient to exclude contamination by adventitious agent. The initial feasibility study was allowed to proceed; however, the Applicant was required to provide data demonstrating that the MCB was free of adventitious agents. This information was submitted on July 3, 2013, and the partial hold was removed on August 1, 2013.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/761049Orig1s000MultidisciplineR.pdf	9/23/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/23/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761049	1561	181	1	1	1	1	1					
207145	Xadago	safinamide	90ENL74SIG	Neurology	small molecule	NDA	6/26/2003		June 26, 2003. The applicant claims June 22, 2003, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was on June 26, 2003, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2015/07/17/2015-02044/determination-of-regulatory-review-period-for-purposes-of-patent-extension-xadago	12/29/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/21/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207145	5017	813						1				
209092	Kisqali	ribociclib	TK8ERE8P56	Oncology	small molecule	NDA	8/26/2010		August 26, 2010. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 26, 2010.	https://www.federalregister.gov/documents/2019/06/11/2019-12305/determination-of-regulatory-review-period-for-purposes-of-patent-extension-kisqali	8/29/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/13/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209092	2391	196				1	1					
208794	Xermelo	telotristat ethyl	8G388563M7	Oncology	small molecule	NDA	1/20/2008		January 20, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 20, 2008.	https://www.federalregister.gov/documents/2018/12/28/2018-28218/determination-of-regulatory-review-period-for-purposes-of-patent-extension-xermelo	3/30/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/28/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208794	3327	335	1	1	1		1					
761032	Siliq	brodalumab	6ZA31Y954Z	Dermatology	antibody	BLA	8/22/2008		August 22, 2008. The applicant claims September 26, 2009, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 22, 2008, which was 30 days after FDA receipt of an earlier IND.	https://www.federalregister.gov/documents/2018/10/23/2018-23058/determination-of-regulatory-review-period-for-purposes-of-patent-extension-siliq	11/16/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/15/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761032	3099	457										
208684	Emflaza	deflazacort	KR5Y26AE4B	Neurology	small molecule	NDA	NA	Ex-US clinical development predates IND	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208684,208685Orig1s000PharmR.pdf Original IND 119258 (Deflazacort for DMD) was received on October 3, 2014. No nonclinical issues were included in the May Proceed letter dated December 2, 2014. Although originally submitted as 505(b)(1) applications, both NDAs were changed to 505(b)(2) applications (November 16, 2016) based on use of published literature. Clinical development was conducted by Marathon under IND 119258. Deflazacort has international approvals for a wide range of conditions. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208684,208685Orig1s000Sumfr.pdf This application contains data from two clinical trials conducted in the 1990s that investigated the use of deflazacort for the treatment of DMD. Study NM-001 was a multicenter, randomized, double-blind, placebo-controlled, 52-week study conducted in the US and Canada. Study NM-001 was a multicenter, randomized, double-blind, placebo-controlled, 52-week study conducted in the US and Canada between 1993 and 1995 by Nordic Merell-Dow. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208684,208685Orig1s000StatR.pdf The first patient was enrolled on April 26, 1993 and the study was completed on April 20, 1995. Deflazacort is a corticosteroid first launched in 1985 by Guidotti in Europe for the oral treatment of allergic asthma, rheumatoid arthritis, arthritis ... FDA DMF: 4922 I # 3/17/1983 SCHERING AG DEFLAZACORT https://pubmed.ncbi.nlm.nih.gov/7117360/ First clinical trial report from 1982	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208684%2C208685Orig1s000StatR.pdf	6/9/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/9/2017	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208684%2C208685Orig1s000TOC.cfm	NA	245	1	1	1			1					
208325	Parsabiv	etelcalcetide	60MEI33FJB	Endocrinology	peptide	NDA	9/19/2010		September 19, 2010. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 19, 2010.	https://www.federalregister.gov/documents/2018/12/28/2018-28221/determination-of-regulatory-review-period-for-purposes-of-patent-extension-parsabiv	8/24/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/7/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208325	2333	533						1				
208745	Trulance	plecanatide	7IK829S2OK	Gastroenterology	peptide	NDA	5/2/2008		May 2, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was May 2, 2008.	https://www.federalregister.gov/documents/2018/12/04/2018-26289/determination-of-regulatory-review-period-for-purposes-of-patent-extension-trulance	1/29/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/19/2017	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208745	3184	356										
209531	Spinraza	nusinersen	529SP3X666	Neurology	oligo	NDA	10/1/2010		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/209531Orig1s000RiskR.pdf The following is a summary of the regulatory history for NDA 209531 relevant to this review: 04/18/2011: Orphan product designation granted for the treatment of spinal muscular atrophy 11/29/2011: Fast track designation granted. https://clinicaltrials.gov/ct2/show/NCT01494701 Actual Study Start Date : November 30, 2011: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/209531Orig1s000Administered.pdf Question 5: Based on the serious and life-threatening nature of SMA and the ISIS 396443 data demonstrating the potential to address an unmet medical need, ISIS 396443 was granted Fast Track designation upon initiation of IND 110,011 in October 2010. Does the Agency agree that a rolling submission for the NDA may be utilized? FDA Response to Question 5: Yes.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/209531Orig1s000MedReviews.pdf	9/23/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/23/2016	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209531	2275	91	1	1	1		1					
209115	Rubraca	rucaparib	8237F3U7EH	Oncology	small molecule	NDA	9/25/2009		September 25, 2009. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 25, 2009.	https://www.federalregister.gov/documents/2018/12/28/2018-28227/determination-of-regulatory-review-period-for-purposes-of-patent-extension-rubraca	6/23/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/19/2016	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209115	2642	179		1		1	1	1				
207695	Eucrisa	crisaborole	Q2847HSR7P	Dermatology	small molecule	NDA	5/31/2008		May 31, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was May 31, 2008.	https://www.federalregister.gov/documents/2019/02/12/2019-01956/determination-of-regulatory-review-period-for-purposes-of-patent-extension-eucrisa	1/7/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/14/2016	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207695	3119	342										
125603	MACI	pork collagen	I8442U2G7J	Orthopedics	protein	BLA	NA	Ex-US clinical development predates IND	https://wayback.archive-it.org/7993/20190425002036/https://www.fda.gov/downloads/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/UCM536121.pdf No IND(s) is associated with this file. All clinical studies were conducted outside of the United States (OUS).	https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/maci-autologous-cultured-chondrocytes-porcine-collagen-membrane	1/4/2016	https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/maci-autologous-cultured-chondrocytes-porcine-collagen-membrane	12/13/2016	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125603	NA	344										
761046	Zinplava	bezlotoxumab	4H5YMK1H2E	Antibacterial	antibody	BLA	11/25/2005		IND submitted November 25, 2005.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/761046Orig1s000MedR.pdf	11/23/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/21/2016	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/761046.cfm	3983	333	1		1		1					
761038	Lartruvo	olaratumab	TT6HN20MVF	Oncology	antibody	BLA	6/30/2006		June 30, 2006. The applicant claims July 1, 2006, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 30, 2006, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2018/10/24/2018-23219/determination-of-regulatory-review-period-for-purposes-of-patent-extension-lartruvo	2/24/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/19/2016	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761038	3764	238	1	1	1	1	1					
206488	Exondys 51	eteplirsen	AIW6036FAS	Neurology	oligo	NDA	10/26/2007		https://www.federalregister.gov/documents/2019/02/11/2019-01851/determination-of-regulatory-review-period-for-purposes-of-patent-extension-exondys-51 June 25, 2010. FDA has verified the applicant's claim that the date the investigational new drug application became effective was June 25, 2010. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488Orig1s000MedR.pdf A Type B (End of Phase 1) meeting was held after the proof of concept study, AVI-4658-13 https://clinicaltrials.gov/ct2/show/NCT00159250 Actual Study Start Date : October 26, 2007	https://clinicaltrials.gov/ct2/show/NCT00159250	6/26/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/19/2016	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488_Exondys_51.cfm	3251	451	1	1	1		1	1				
208471	Adlyxin	lixisenatide	74OG2B801U	Endocrinology	peptide	BLA	7/8/2001		July 8, 2001. FDA has verified the applicant's claim that the date the investigational new drug application became effective was July 8, 2001.	https://www.federalregister.gov/documents/2018/12/26/2018-27807/determination-of-regulatory-review-period-for-purposes-of-patent-extension-adlyxin	7/27/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/27/2016	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208471	5498	366										
208073	Xiidra	lifitegrast	03BES1962W	Opthamology	small molecule	NDA	7/1/2008		Lifitegrast ophthalmic solution has been studied under IND 77885 which was opened in July 2008, with the submission of a protocol for a Phase 1 study in healthy subjects.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/208073Orig1s000MedR.pdf	2/25/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/11/2016	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208073	2932	502	1				1		1			
208341	Epclusa	velpatasvir	KCU0C7RS7Z	Antiviral	small molecule	NDA	11/6/2012		An Investigational New Drug application (IND) for the SOF/VEL FDC was submitted on August 13, 2013 by Gilead Sciences, Inc. After a 30-day safety review, it was determined the Sponsor may proceed with the proposed clinical investigation under IND 118605 on September 12, 2013. VEL does not prolong QTc to any clinically relevant extent. Please refer to the QT/RT review by Moh Jee Ng for additional details (IND 115670, April 15, 2015). https://clinicaltrials.gov/ct2/show/NCT01740791 Actual Study Start Date : November 6, 2012	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/208341Orig1s000MedR.pdf	10/28/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/28/2016	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208341	1330	244		1	1	1						
208547	NETSPOT	gallium 68 dotatate	9L17YOH71P	Oncology	peptide	NDA	NA	Original IND submission date not provided	drug development was conducted under IND 122818. The clinical data from VUMC was conducted under IND 111972. The application contains sufficient evidence based upon the totality of the data contained within the submitted literature and VUMC clinical trial that the drug has been shown to be effective as a diagnostic radiopharmaceutical for the NET population. 7/1/14: DMP agreed that the sponsor could submit an NDA based upon literature, preferably meta-analysis if there are sufficient data, if not, a systematic review would be acceptable, and supported by the results of the expanded access study conducted at Vanderbilt University Medical Center.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/208547Orig1s000MedR.pdf	7/1/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/1/2016	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208547	NA	336	1			1				1		
207999	Ocaliva	obeticholic acid	0462Z4S4OZ	Gastroenterology	small molecule	NDA	3/1/2006		March 1, 2006. The applicant claims February 26, 2006, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 1, 2006, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2018/12/04/2018-26288/determination-of-regulatory-review-period-for-purposes-of-patent-extension-ocaliva	6/29/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/27/2016	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207999	3740	333	1	1	1		1	1				
208054	Axumin	fluciclovine F 18	38R1QOL1ZE	Oncology	small molecule	NDA	6/10/2005		June 10, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 10, 2005	https://www.federalregister.gov/documents/2018/01/17/2018-00684/determination-of-regulatory-review-period-for-purposes-of-patent-extension-axumin	9/28/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/27/2016	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208054	4004	242				1					1	
761034	Tecentriq	atezolizumab	52CMI0WC3Y	Oncology	antibody	BLA	5/11/2011		May 11, 2011. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 11, 2011.	https://www.federalregister.gov/documents/2018/10/22/2018-22957/determination-of-regulatory-review-period-for-purposes-of-patent-extension-tecentriq	1/12/2016	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/18/2016	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761034	1834	127				1	1	1				
207318	Nuplazid	pimavanserin	J2I63PD0IK	Neurology	small molecule	NDA	11/9/2003		November 9, 2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was November 9, 2003.	https://www.federalregister.gov/documents/2018/10/23/2018-23057/determination-of-regulatory-review-period-for-purposes-of-patent-extension-nuplazid	9/1/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/29/2016	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207318	4555	241				1	1			1		
208573	Venclexta	venetoclax	N54AIC43PW	Oncology	small molecule	NDA	11/28/2010		The trials for the treatment of patients with relapsed/refractory CLL were conducted under IND 110159, which was opened in the US on November 28, 2010. Due to tumor lysis syndrome resulting in deaths and renal failure requiring dialysis, the IND was placed on partial clinical hold on enrollment for studies in CLL on December 17, 2012. The hold was removed on May 3, 2013 after implementation of risk stratification and prophylaxis for TLS.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/208573Orig1s000MedR.pdf	10/29/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/11/2016	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208573	1961	165	1	1		1	1	1				
208114	Defitelio	defibrotide sodium	L7CHH2B2J0	Hematology	polymer	NDA	6/15/1997		1997: The first US IND for defibrotide opened for VOD patients with multi-organ failure at Dana Farber Cancer Institute. IND 62118(Commercial IND) was submitted to the Agency on 15 December 2003. Defibrotide was produced in 1983, and oral an injectable formulation developed by Gentium S.p.A.(formerly Crinos-Villa Guardia)[Como]-Italy) received marketing authorization(MA) in Italy for prophylaxis of deep-vein thrombosis and treatment of thrombophlebitis(Procilde®, Noravid®).	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/208114Orig1s000MedR.pdf	7/31/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/30/2016	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208114	6863	243	1	1	1		1					
761033	Cinqair	reslizumab	3SA26E427H	Respiratory	antibody	BLA	9/18/1997		https://www.federalregister.gov/documents/2017/08/07/2017-16516/determination-of-regulatory-review-period-for-purposes-of-patent-extension-cinqair August 31, 2000. The applicant claims February 15, 2008, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 31, 2000, which was 30 days after FDA receipt of the first IND. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/761033Orig1s000ClinPharmR.pdf Study 096-350 (Study 001) Study Type: Phase 1 single dose, dose-ranging PK, PD and safety study in adult patients with severe asthma Study Dates: 09/18/1997 – 11/11/1999 Sponsor: Schering-Plough Corporation Title: Rising single-Dose, safety, tolerance, and pharmacokinetics of SCH 55700 in subjects with severe asthma	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/761033Orig1s000ClinPharmR.pdf	3/30/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/23/2016	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761033	6761	359					1					
125521	Taltz	ixekizumab	BTY153760O	Rheumatology	antibody	BLA	12/1/2007		December 1, 2007. The applicant claims December 2, 2007, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 1, 2007, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2018/10/26/2018-23438/determination-of-regulatory-review-period-for-purposes-of-patent-extension-taltz	3/23/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/22/2016	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125521	3034	365										
125509	Anthim	obiltoxaximab	29ZSDNL48C	Antibacterial	antibody	BLA	8/4/2005		IND Filed 24 Feb 2005. IND effective 4 Aug 2005.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/125509Orig1s000MedR.pdf	3/20/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/18/2016	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125509	3879	364	1	1					1			1

App	Product	NME ingredients	unii	Therapeutic Class	Molecule Type	App Type	IND date	IND date note	indDateComment	IND date ref	App submitted date	App submitted date ref	App approval date	App ref	Days in clinical development	Days in review	First	Orphan	Fast track	Break-through	Priority	Acceler-ated	Non-first cycle	Black box	Diagnostic imaging	Animal rule
205836	Briviact	brivaracetam	U863JGG2IA	Neurology	small molecule	NDA	8/12/2004		August 12, 2004. The applicant claims November 30, 2008, as the date the investigational new drug application (IND) became effective. However, according to FDA records, this IND was not the first IND received for this active ingredient. In general, FDA has used the first IND submitted for investigation of the active ingredient of the drug product as the beginning of the testing phase, if information derived from this first IND was or could have been relied on or was relevant for approval to market the drug product. FDA records indicate that the effective date of the first IND for brivaracetam was August 12, 2004, which was 30 days after FDA receipt of this first IND. This is the same IND and the same date FDA determined was the beginning of the regulatory review period for BRIVIACT ORAL TABLETS approved under NDA 205836 and for BRIVIACT ORAL SOLUTION approved under NDA 205838. The regulatory review period determinations for BRIVIACT ORAL TABLETS and BRIVIACT ORAL SOLUTION are publishing in this issue of the	https://www.federalregister.gov/documents/2019/12/12/2019-26812/determination-of-regulatory-review-period-for-purposes-of-patent-extension-briviact-injection-new	11/24/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/18/2016	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205836	4207	451										
208261	Zepatier	elbasvir|grazoprevir	632L571YDK|4O2AB118LA	Antiviral	small molecule	NDA	6/28/2009		https://www.federalregister.gov/documents/2018/01/30/2018-01642/determination-of-regulatory-review-period-for-purposes-of-patent-extension-zepatier December 22, 2010. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 22, 2010. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/208261Orig1s000MedR.pdf Merck submitted an initial IND application for GZR (IND 110261) and for EBR (IND 114298) for treatment of chronic HCV infection on November 22, 2010, and March 22, 2012, respectively, after conducting preliminary Phase 1 studies for each in Belgium. Development of the combination of GZR and EBR occurred under IND 110261. MK-5172-001 for EBR and MK-8742-001 for GZR.	https://www.pmda.go.jp/drugs/2016/P20161013003/170050000_22800AMX00710_K101_1.pdf	5/28/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/28/2016	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208261	2405	245				1	1					
207988	Zurampic	lesinurad	09ERP08I3W	Hematology	small molecule	NDA	10/31/2009		October 31, 2009. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 31, 2009.	https://www.federalregister.gov/documents/2018/01/22/2018-00992/determination-of-regulatory-review-period-for-purposes-of-patent-extension-zurampic	12/29/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/22/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207988	2243	358								1		
207947	Uptravi	selexipag	5EXC0E384L	Respiratory	small molecule	NDA	10/29/2009		October 29, 2009. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 29, 2009.	https://www.federalregister.gov/documents/2018/01/30/2018-01637/determination-of-regulatory-review-period-for-purposes-of-patent-extension-uptravi	12/22/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/21/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207947	2244	364		1								
22225	Bridion	sugammadex	361LPM2T56	Neurology	small molecule	NDA	4/13/2004		April 13, 2004. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 13, 2004.	https://www.federalregister.gov/documents/2018/02/15/2018-03137/determination-of-regulatory-review-period-for-purposes-of-patent-extension-bridion	10/31/2007	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/15/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022225	4263	2967	1				1		1			
208434	Alecensa	alectinib	LIJ4CT1Z3Y	Oncology	small molecule	NDA	10/28/2011		On September 30, 2011, IND 111723 was submitted to the FDA and was allowed to proceed on October 28, 2011.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/208434Orig1s000SumR.pdf	7/6/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/11/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208434	1505	158		1		1	1	1				
125561	Kanuma	sebelipase alfa	K4YTU42T8G	Hepatology	enzyme	BLA	12/22/2010		December 22, 2010 Receipt of initial IND application Intended for the treatment of LAL deficiency	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/125561Orig1s000MedR.pdf	1/8/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/8/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125561	1812	334	1	1	1	1	1					
761035	Empliciti	elotuzumab	1351PE5UGS	Oncology	antibody	BLA	8/11/2006		August 11, 2006. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 11, 2006.	https://www.federalregister.gov/documents/2017/01/09/2017-00108/determination-of-regulatory-review-period-for-purposes-of-patent-extension-empliciti	6/29/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/30/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761035	3398	154	1	1		1	1					
125547	Portrazza	necitumumab	2BT4C47RUI	Oncology	antibody	BLA	12/19/2008		December 19, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 19, 2008.	https://www.federalregister.gov/documents/2018/02/20/2018-03345/determination-of-regulatory-review-period-for-purposes-of-patent-extension-portrazza	12/2/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/24/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125547	2531	357		1	1					1		
208462	Ninlaro	ixazomib	71050168A2	Oncology	small molecule	NDA	12/10/2008		December 10, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 10, 2008.	https://www.federalregister.gov/documents/2018/01/22/2018-00994/determination-of-regulatory-review-period-for-purposes-of-patent-extension-ninlaro	7/10/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/20/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208462	2536	133		1			1					
761036	Darzalex	daratumumab	4Z63YK6E0E	Oncology	antibody	BLA	7/28/2010		July 28, 2010. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 28, 2010.	https://www.federalregister.gov/documents/2018/02/20/2018-03342/determination-of-regulatory-review-period-for-purposes-of-patent-extension-darzalex	7/9/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/16/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761036	1937	130	1	1	1	1	1	1				
208065	Tagrisso	osimertinib	3C06JJ0Z2O	Oncology	small molecule	NDA	3/6/2013		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/208065Orig1s000SumR.pdf On July 11, 2013, FDA issued a Safe May Proceed memo for the IND submitted June 11, 2013. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/208065Orig1s000MedR.pdf Discussions included nonclinical toxicology studies, dose selection strategy in first-in-human Study D5160C00001 (AURA) AURA Phase 1 First patient dosed: 6 March 2013 (80 mg subset in dose expansion: 2 September 2013) https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/208065Orig1s000ClinPharmR.pdf Study AURA I Capsule: 20, 40, 80, 160 and 240 Tablet: 80 https://clinicaltrials.gov/ct2/show/NCT01802632 AZD9291 First Time In Patients Ascending Dose Study (AURA) Actual Study Start Date : March 4, 2013 Other Study ID Numbers: D5160C00001	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/208065Orig1s000MedR.pdf	6/5/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/13/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208065	984	161		1	1	1	1	1				
206192	Cotellic	cobimetinib	ER29L26N1X	Oncology	small molecule	NDA	1/19/2007		January 19, 2007. FDA has verified the Exelixis, Inc. claim that January 19, 2007, is the date the investigational new drug application became effective.	https://www.federalregister.gov/documents/2018/02/16/2018-03218/determination-of-regulatory-review-period-for-purposes-of-patent-extension-cotellic	12/11/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/10/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206192	3217	334		1	1		1					
207561	Genvoya	tenofovir alafenamide fumarate	FWF6Q91TZO	Antiviral	small molecule	NDA	1/28/2002		January 28, 2002. The applicant claims January 25, 2002, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 28, 2002, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.	https://www.federalregister.gov/documents/2018/02/07/2018-02403/determination-of-regulatory-review-period-for-purposes-of-patent-extension-genvoya	11/5/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/5/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207561	5029	365			1					1		
125526	Nucala	mepolizumab	90Z2UF0E52	Respiratory	antibody	BLA	1/22/1997		January 22, 1997. The applicant claims January 21, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 22, 1997, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2016/12/13/2016-29838/determination-of-regulatory-review-period-for-purposes-of-patent-extension-nucala	11/4/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/4/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125526	6860	365	1									
125518	Imlygic	talimogene laherparepvec	07730V90L6	Oncology	virus	BLA	5/25/2005		May 25, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 25, 2005.	https://www.federalregister.gov/documents/2016/12/28/2016-31322/determination-of-regulatory-review-period-for-purposes-of-patent-extension-imlygic	7/28/2014	https://wayback.archive-it.org/7993/20190425013447/https://www.fda.gov/downloads/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/UCM473103.pdf	10/27/2015	https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/imlygic-talimogene-laherparepvec	3807	456	1									
207953	Yondelis	trabectedin	ID0YZQ2TCP	Oncology	small molecule	NDA	5/10/1996		May 10, 1996. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 10, 1996.	https://www.federalregister.gov/documents/2017/11/28/2017-25683/determination-of-regulatory-review-period-for-purposes-of-patent-extension-yondelis	11/24/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/23/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207953	7105	333		1			1					
125513	Strensiq	asfotase alfa	Z633861EIM	Endocrinology	enzyme	BLA	7/3/2008		July 3, 2008. The applicant claims July 4, 2008, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 3, 2008, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2018/02/09/2018-02588/determination-of-regulatory-review-period-for-purposes-of-patent-extension-strensiq	12/23/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/23/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125513	2668	304	1	1	1	1	1					
205739	Veltassa	patiromer	1FQ2RY5YHH	Endocrinology	polymer	NDA	1/9/2008		January 9, 2008. FDA has verified the applicant's claim that January 9, 2008, is the date the investigational new drug application (IND) became effective.	https://www.federalregister.gov/documents/2017/11/29/2017-25761/determination-of-regulatory-review-period-for-purposes-of-patent-extension-veltassa	10/21/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/21/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205739	2842	365								1		
761025	Praxbind	idarucizumab	97RWB5S1U6	Hematology	antibody	BLA	9/1/2012		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/761025Orig1s000SumR.pdf Pre-IND meetings were held on August 10, 2011, January 31, 2013 and February 11, 2014 under IND 112278. The IND was accepted by the Division of Hematology Products on 12/23/2013. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/761025Orig1s000ClinPharmR.pdf 2.1.2.1 Study 1321.1. Study 1321.1 was a safety and tolerability study in healthy male volunteers. https://clinicaltrials.gov/ct2/show/NCT01688830 Study Start Date : September 2012 Other Study ID Numbers: 1321.1	https://clinicaltrials.gov/ct2/show/NCT01688830	2/19/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/16/2015	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/0761025Orig1000TOC.cfm	1140	239	1	1		1	1	1				
207533	Aristada	aripiprazole lauroxil	B786J7A343	Neurology	small molecule	NDA	7/16/2010		Studies with aripiprazole lauroxil for treatment of schizophrenia were conducted under an Investigational New Drug Application (IND #107,249) submitted to the Division of Psychiatry Products on July 16, 2010 in sequence 0002. The proposed application was discussed at the pre-NDA Meeting held on May 19, 2014. In vivo conversion of aripiprazole lauroxil to aripiprazole is governed by dissolution of the drug particles from the injection site followed by hydrolysis, generating lauric acid and N-hydroxymethyl aripiprazole. The covalently bonded N-hydroxymethyl aripiprazole is then converted to aripiprazole following water-mediated hydrolysis, releasing aripiprazole and formaldehyde. The exposure of aripiprazole following injection of aripiprazole lauroxil is qualitatively similar to that following oral administration of aripiprazole tablets.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/207533Orig1s000MedR.pdf	8/22/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/5/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207533	1907	409								1		
203314	Tresiba	insulin degludec	54Q18076QB	Endocrinology	peptide	BLA	10/5/2007		October 5, 2007. The applicant claims September 5, 2007, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 5, 2007, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2016/12/02/2016-28939/determination-of-regulatory-review-period-for-purposes-of-patent-extension-tresiba	9/29/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/25/2015	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/203313and203314Orig1s000TOC.cfm	2912	1457							1			
207981	Lonsurf	tipiracil	NGO10K751P	Oncology	small molecule	NDA	1/28/1999		January 28, 1999. FDA has verified the Taiho Pharmaceutical Co., Ltd. claim that January 28, 1999, is the date the investigational new drug application (IND) became effective.	https://www.federalregister.gov/documents/2018/01/30/2018-01641/determination-of-regulatory-review-period-for-purposes-of-patent-extension-lonsurf	12/19/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/22/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207981	6081	277			1							
204370	Vraylar	cariprazine	F6RJL8B278	Neurology	small molecule	NDA	6/21/2005		June 21, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 21, 2005.	https://www.federalregister.gov/documents/2018/01/26/2018-01368/determination-of-regulatory-review-period-for-purposes-of-patent-extension-vraylar	11/19/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/17/2015	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/204370Orig2s000TOC.cfm	3740	1032							1			
208169	Xuriden	uridine triacetate	2WP61F175M	Hematology	small molecule	NDA	6/4/1992		June 4, 1992. The applicant claims May 4, 1992, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 4, 1992, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2017/11/29/2017-25770/determination-of-regulatory-review-period-for-purposes-of-patent-extension-xuriden	1/8/2015	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/4/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208169	8492	239	1	1		1	1					
206500	Varubi	rolapitant	NLE429IZUC	Oncology	small molecule	NDA	4/8/2007		April 8, 2007. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 8, 2007.	https://www.federalregister.gov/documents/2018/01/26/2018-01373/determination-of-regulatory-review-period-for-purposes-of-patent-extension-varubi	9/5/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/1/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206500	3068	361										
125522	Repatha	evolocumab	LKC0U3A8NJ	Endocrinology	antibody	BLA	6/14/2009		June 14, 2009. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 14, 2009.	https://www.federalregister.gov/documents/2016/10/19/2016-25221/determination-of-regulatory-review-period-for-purposes-of-patent-extension-repatha	8/27/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/27/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125522	2265	365		1								
22526	Addyi	flibanserin	37JK4STR6Z	Neurology	small molecule	NDA	11/15/1996		November 15, 1996. FDA has verified Sprout Pharmaceuticals, Inc. claims that November 15, 1996, is the date the investigational new drug application became effective.	https://www.federalregister.gov/documents/2018/02/15/2018-03130/determination-of-regulatory-review-period-for-purposes-of-patent-extension-addyi	10/27/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/18/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022526	6850	2121	1						1			
206843	Daklinza	daclatasvir	LI2427F9CI	Antiviral	small molecule	NDA	11/17/2007		November 17, 2007. The applicant claims November 16, 2007, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 17, 2007, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2018/01/17/2018-00675/determination-of-regulatory-review-period-for-purposes-of-patent-extension-daklinza	3/31/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/24/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206843	2806	480			1		1		1			
205266	Odomzo	sonidegib	0RLU3VTK5M	Oncology	small molecule	NDA	12/15/2008		December 15, 2008. FDA has verified the applicant's claim that December 15, 2008, is the date the investigational new drug application (IND) became effective.	https://www.federalregister.gov/documents/2018/02/09/2018-02658/determination-of-regulatory-review-period-for-purposes-of-patent-extension-odomzo	9/26/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/24/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205266	2412	301								1		
125559	Praluent	alirocumab	PP0SHH6V16	Endocrinology	antibody	BLA	11/12/2009		12 Nov 2009 US IND opened (105574)	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/125559Orig1s000MedR.pdf	11/24/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/24/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125559	2080	242	1				1					
205422	Rexulti	brexpiprazole	2J3YBM1K8C	Neurology	small molecule	NDA	4/23/2008		April 23, 2008. The applicant claims April 20, 2008, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 23, 2008, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2017/11/29/2017-25772/determination-of-regulatory-review-period-for-purposes-of-patent-extension-rexulti	7/11/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/10/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205422	2634	364								1		
207620	Entresto	sacubitril	17ERJ0MKGI	Cardiology	small molecule	NDA	11/25/2006		November 25, 2006. Novartis Pharmaceuticals Corporation claims that April 8, 2007, is the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 25,	https://www.federalregister.gov/documents/2018/02/09/2018-02592/determination-of-regulatory-review-period-for-purposes-of-patent-extension-entresto	12/17/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/7/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207620	3146	202	1		1		1			1		

App	Product	NME ingredients	unii	Therapeutic Class	Molecule Type	App Type	IND date	IND date note	indDateComment	IND date ref	App submitted date	App submitted date ref	App approval date	App ref	Days in clinical development	Days in review	First	Orphan	Fast track	Break-through	Priority	Acceler-ated	Non-first cycle	Black box	Diagnostic imaging	Animal rule
206038	Orkambi	lumacaftor	EGP8L81APK	Respiratory	small molecule	NDA	11/18/2007		November 18, 2007. FDA has verified the applicant's claim that November 18, 2007, is the date the investigational new drug application (IND) became effective.	https://www.federalregister.gov/documents/2018/02/15/2018-03127/determination-of-regulatory-review-period-for-purposes-of-patent-extension-orkambi	11/5/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/2/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206038	2783	239	1	1	1	1	1					
204958	Kengreal	cangrelor	6AQ1Y404U7	Cardiology	small molecule	NDA	9/19/1998		September 19, 1998. The applicant claims August 20, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 19, 1998, which	https://www.federalregister.gov/documents/2017/08/30/2017-18380/determination-of-regulatory-review-period-for-purposes-of-patent-extension-kengreal	4/30/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/22/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204958	6120	783							1			
206940	Viberzi	eluxadoline	45TPJ4MBQ1	Gastroenterology	small molecule	NDA	12/21/2007		December 21, 2007. FDA has verified the applicant's claim that December 21, 2007, is the date the investigational new drug application (IND) became effective.	https://www.federalregister.gov/documents/2018/02/05/2018-02187/determination-of-regulatory-review-period-for-purposes-of-patent-extension-viberzi	6/27/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/27/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206940	2714	334			1		1					
206333	Kybella	deoxycholic acid	005990WHZZ	Endocrinology	small molecule	NDA	12/5/2007		The applicant started development of ATX-101 as a nonsurgical treatment modality for lipomas (under IND opened in 2006) and unwanted submental fat (under IND 79,726 opened in 2007) for both, US and European markets. The lipoma development was later abandoned and IND was inactivated in 2010. IND 79726 (12-05-2007), reduction of localized subcutaneous fat.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/206333Orig1s000PharmR.pdf	5/13/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/29/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206333	2702	351										
206143	Corlanor	ivabradine	3H48L0LPZQ	Cardiology	small molecule	NDA	NA	Ex-US clinical development predates IND	No studies were conducted under an IND Corlanor (ivabradine) is a first-in-class NME that is not currently marketed in the US. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/206143Orig1s000MedR.pdf However, as of December 2013, has been approved in 88 countries outside the United States (US) for the treatment of chronic heart failure and in 102 countries for the treatment of angina.	https://www.federalregister.gov/documents/2018/02/01/2018-01979/determination-of-regulatory-review-period-for-purposes-of-patent-extension-corlanor	6/27/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/15/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206143	NA	292	1		1		1					
125562	Anthrasil	anthrax immune globulin human	VKZ83S945Z	Antibacterial	antibody	BLA	2/23/2006		Under the FDA-authorized emergency use BB-IND 12953, one dose of AIGIV was administered to a patient with laboratory-confirmed, naturally acquired inhalation anthrax on February 23, 2006. Cangene held a pre-IND meeting with CBER regarding the development plan for Anthrax Immune Globulin on 26 August 2004, and received considerable input from CBER regarding product development at that time.	https://wayback.archive-it.org/7993/20190423063458/https://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/UCM567443.zip	3/10/2014	https://wayback.archive-it.org/7993/20190423063458/https://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/UCM567443.zip	3/24/2015	https://wayback.archive-it.org/7993/20190423063458/https://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/ucm441234.htm	3316	379		1			1					1
205750	Cholbam	cholic acid	G1JO7801AE	Gastroenterology	small molecule	NDA	6/5/1994		BACKGROUND: On June 5, 1994, Dr. James E. Heubi submitted IND 45,470 for Cholic Acid. On August 6, 2004, R & R Registrations submitted ...	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/205750Orig1s000AdminCorres.pdf	11/21/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/17/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205750	7590	481		1			1					
125516	Unituxin	dinutuximab	7SQY4ZUD30	Oncology	antibody	BLA	12/4/1991		12/4/1991 IND Submission Application for IND 4308 submitted by CTEP.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/125516Orig1s000MedR.pdf	4/11/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/10/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125516	8497	333	1	1			1			1		
207500	Cresemba	isavuconazonium sulfate	31Q44514JV	Antibacterial	small molecule	NDA	7/10/2005		July 10, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 10, 2005.	https://www.federalregister.gov/documents/2018/01/31/2018-01892/determination-of-regulatory-review-period-for-purposes-of-patent-extension-cresemba-new-drug	7/8/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/6/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207500	3526	241		1			1					
206494	Avycaz	avibactam	7352665165	Antibacterial	small molecule	NDA	2/5/2008		February 5, 2008. FDA has verified the applicant's claim that February 5, 2008, is the date the investigational new drug application (IND) became effective.	https://www.federalregister.gov/documents/2018/01/17/2018-00678/determination-of-regulatory-review-period-for-purposes-of-patent-extension-avycaz	6/25/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/25/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206494	2577	245			1		1					
205353	Farydak	panobinostat	9647FM7Y3Z	Oncology	small molecule	NDA	4/15/2003		April 15, 2003. The applicant claims April 15, 2002, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 15, 2003, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.	https://www.federalregister.gov/documents/2018/02/13/2018-02868/determination-of-regulatory-review-period-for-purposes-of-patent-extension-farydak	3/24/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/23/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205353	4332	336		1			1	1		1		
206947	Lenvima	lenvatinib	EE083865G2	Oncology	small molecule	NDA	4/28/2005		April 28, 2005. FDA has verified the applicant's claim that April 28, 2005, is the date the investigational new drug application (IND) became effective.	https://www.federalregister.gov/documents/2018/01/31/2018-01920/determination-of-regulatory-review-period-for-purposes-of-patent-extension-lenvima	8/14/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/13/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206947	3578	183		1			1					
207103	Ibrance	palbociclib	G9ZF61LE7G	Oncology	small molecule	NDA	4/9/2004		April 9, 2004. FDA has verified the Warner-Lambert Company, LLC, claim that April 9, 2004, is the date the investigational new drug application (IND) became effective.	https://www.federalregister.gov/documents/2018/02/14/2018-03029/determination-of-regulatory-review-period-for-purposes-of-patent-extension-ibrance	8/13/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/3/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207103	3952	174	1			1	1	1				
125511	Natpara	parathyroid hormone	N19A0T0E5J	Endocrinology	peptide	BLA	3/3/1995		March 3, 1995. The applicant claims January 31, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 3, 1995, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2017/06/15/2017-12359/determination-of-regulatory-review-period-for-purposes-of-patent-extension-natpara	10/24/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/23/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125511	7266	456		1								
125504	Cosentyx	secukinumab	DLG4EML025	Dermatology	antibody	BLA	10/21/2005		October 21, 2005. The applicant claims December 17, 2006, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 21, 2005, which was thirty days after FDA receipt of an earlier IND.	https://www.federalregister.gov/documents/2016/12/20/2016-30528/determination-of-regulatory-review-period-for-purposes-of-patent-extension-cosentyx	10/24/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/21/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125504	3379	454	1									
206316	Savaysa	edoxaban	NDU3J18APO	Cardiology	small molecule	NDA	7/1/2004		July 1, 2004. FDA has verified the applicant's claim that July 1, 2004, is the date the investigational new drug application (IND) became effective.	https://www.federalregister.gov/documents/2017/11/28/2017-25703/determination-of-regulatory-review-period-for-purposes-of-patent-extension-savaysa	1/8/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/8/2015	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206316	3843	365								1		
125554	Opdivo	nivolumab	31YO63LBSN	Oncology	antibody	BLA	7/28/2006		July 28, 2006. The applicants claim July 29, 2006, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 28, 2006, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.	https://www.federalregister.gov/documents/2016/12/02/2016-28917/determination-of-regulatory-review-period-for-purposes-of-patent-extension-opdivo	7/30/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/22/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125554	3069	145		1	1	1	1	1				
206162	Lynparza	olaparib	WOH1JD9AR8	Oncology	small molecule	NDA	7/4/2005		https://www.federalregister.gov/documents/2018/02/09/2018-02591/determination-of-regulatory-review-period-for-purposes-of-patent-extension-lynparza September 22, 2006. FDA has verified the applicant's claim that September 22, 2006, is the date the investigational new drug application (IND) became effective. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/206162Orig1s000ClinPharmR.pdf Phase 1, single and multiple dose escalation, safety and tolerability trial in Japanese patients (N=12) D0810C00001 (Trial 1) https://clinicaltrials.gov/ct2/show/NCT00572364 Study Start Date : November 2007 https://clinicaltrials.gov/ct2/show/NCT00516373 A Phase I, Pharmacokinetic and Biological Evaluation of a Small Molecule Inhibitor of Poly ADP-Ribose Polymerase-1 (PARP-1), KU-0059436, in Patients With Advanced Tumours. Actual Study Start Date : July 4, 2005	https://clinicaltrials.gov/ct2/show/NCT00516373	2/3/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/19/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206162	3455	319	1	1			1	1				
206829	Zerbaxa	ceftolozane	37A4IES95Q	Antibacterial	small molecule	NDA	7/5/2008		July 5, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 5, 2008.	https://www.federalregister.gov/documents/2017/11/28/2017-25682/determination-of-regulatory-review-period-for-purposes-of-patent-extension-zerbaxa	4/21/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/19/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206829	2358	242			1		1					
206619	Viekira Pak	ombitasvir|paritaprevir|dasabuvir	2302768XJ8|OU2YM37K86|DE54EQW8T1	Antiviral	small molecule	NDA	6/4/2008		https://www.federalregister.gov/documents/2018/01/30/2018-01651/determination-of-regulatory-review-period-for-purposes-of-patent-extension-viekira-pak June 4, 2008. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/206619Orig1s000MedR.pdf FDA has verified the applicant's claim that June 4, 2008, is the date the investigational new drug application (IND) became effective. Individual INDs for paritaprevir, ombitasvir and dasabuvir were submitted in 2010.	https://www.federalregister.gov/documents/2018/01/30/2018-01651/determination-of-regulatory-review-period-for-purposes-of-patent-extension-viekira-pak	4/21/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/19/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206619	2389	242	1		1	1	1					
206426	Rapivab	peramivir	QW7Y7ZR15U	Antiviral	small molecule	NDA	12/21/2005		December 21, 2005. FDA has verified the BioCryst Pharmaceuticals, Inc. claims that December 21, 2005, is the date the investigational new drug application (IND) became effective.	https://www.federalregister.gov/documents/2017/11/28/2017-25676/determination-of-regulatory-review-period-for-purposes-of-patent-extension-rapivab	12/23/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/19/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206426	3285	361			1							
206307	Xtoro	finafloxacin	D26OSN9Q4R	Antibacterial	small molecule	NDA	8/2/2007		https://www.federalregister.gov/documents/2017/08/30/2017-18379/determination-of-regulatory-review-period-for-purposes-of-patent-extension-xtoro October 26, 2009. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 26, 2009. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3165282/ Human Pharmacokinetics and Safety Profile of Finafloxacin, a New Fluoroquinolone Antibiotic, in Healthy Volunteers. It was carried out in accordance with good clinical practice (guideline CPMP/ICH/135/95), from 2 August 2007 to 27 March 2008.	https://clinicaltrials.gov/ct2/show/NCT00483158	4/25/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/17/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206307	2694	236					1					
125557	Blincyto	blinatumomab	4FR53SIF3A	Oncology	antibody	BLA	6/1/2004		February 15, 2007. FDA has verified the applicant's claims that the date the investigational new drug application became effective was on February 15, 2007. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125557Orig1s000MedRedt.pdf IND 100135 was submitted 8/18/2006 by MedImmune, placed on hold 9/15/2006, discussed at a Type A meeting in 10/25/2006, and finally allowed to proceed in 2/15/2007. Protocol MT103-104 (Protocol 104) - An Open-Label, Multi-Center Phase 1 Study to Investigate the Tolerability and Safety of a Continuous Infusion of the Bispecific T-Cell Engager MT103 in Subjects With Relapsed Non-Hodgkin's Lymphoma https://clinicaltrials.gov/ct2/show/NCT00274742 Study Start Date : June 2004	https://clinicaltrials.gov/ct2/show/NCT00274742	9/19/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/3/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125557	3837	75	1	1		1	1	1		1		
22535	Esbriet	pirfenidone	D7NLD2JX7U	Respiratory	small molecule	NDA	9/29/1973		September 29, 1973. The applicant claims August 1, 1973, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 29, 1973, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2018/02/22/2018-03612/determination-of-regulatory-review-period-for-purposes-of-patent-extension-esbriet	11/4/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/15/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022535	14991	1806	1	1	1	1	1		1			
205832	Ofev	nintedanib	G6HRD2P839	Respiratory	small molecule	NDA	11/1/2002		https://www.federalregister.gov/documents/2018/02/22/2018-03606/determination-of-regulatory-review-period-for-purposes-of-patent-extension-ofev April 7, 2005. The applicant claims April 8, 2005, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 7, 2005, which was 30 days after FDA receipt of the IND. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/205832Orig1s000ClinPharmR.pdf Four Phase 1 studies characterized the single and/or multiple-dose PK of nintedanib. 1199.1: Phase I monotherapy https://clinicaltrials.gov/ct2/show/NCT01951846 Other Study ID Numbers: 1199.1 To Determine the Maximum Tolerated Dose (MTD) of BIBF 1120 in Patients With Solid Tumours Study Start Date : November 2002	https://clinicaltrials.gov/ct2/show/NCT01951846	5/2/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/15/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205832	4366	166	1	1	1	1	1					
203684	Lumason	sulfur hexafluoride	WS7LR3I1D6	Cardiology	small molecule	NDA	1/26/1995		January 26, 1995. The applicant claims December 23, 1994, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 26, 1995, which was 30 days after FDA receipt of the IND. NOTE: Original medical uses extend back to at least 1976 https://pubmed.ncbi.nlm.nih.gov/798394/	https://www.federalregister.gov/documents/2016/09/16/2016-22345/determination-of-regulatory-review-period-for-purposes-of-patent-extension-lumason	12/21/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/10/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203684	7197	1024							1	1	1	
205718	Akynzeo	netupitant	7732P08TIR	Oncology	small molecule	NDA	9/14/2006		https://www.federalregister.gov/documents/2018/02/12/2018-02756/determination-of-regulatory-review-period-for-purposes-of-patent-extension-akynzeo September 10, 2009. FDA has verified the applicant's claim that September 10, 2009, is the date the investigational new drug application (IND) became effective. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/205718Orig1s000MedR.pdf IND submitted Sept. 14, 2006 (IND 73,493) Single-dose phase 1 netupitant + palonosetron PK drug-drug interaction study NETU-06-06 in healthy subjects	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/205718Orig1s000MedR.pdf	9/27/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/10/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205718	2948	378										
205834	Harvoni	ledipasvir	013TE6E4WV	Antiviral	small molecule	NDA	4/30/2010		An Investigational New Drug application (IND) for the LDV/SOF was submitted on May 31, 2012 by Gilead Sciences, Inc. After a 30-day safety review, it was determined the Sponsor may proceed with the proposed clinical investigation under IND 115268 in a letter signed July 2, 2012. IND 108,214 for LDV was submitted ~2010? https://clinicaltrials.gov/ct2/show/NCT01193478. Initial clinical trial was Single dose study GS-US-256-0101 --- dates uncertain. https://www.ema.europa.eu/en/documents/assessment-report/harvoni-epar-public-assessment-report_en.pdf. GS-US-256-0101 Human Plasma LDV 30 Apr 2010 through 15 Jun 2010 https://www.pmda.go.jp/drugs/2015/P20150615003/230867000_22700AMX00691_K100_1.pdf	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/205834Orig1s000MedR.pdf	2/10/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/10/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205834	1624	242	1		1	1	1					
125469	Trulicity	dulaglutide	WTT295HSY5	Endocrinology	peptide	BLA	9/4/2005		September 4, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 4, 2005.	https://www.federalregister.gov/documents/2016/12/19/2016-30399/determination-of-regulatory-review-period-for-purposes-of-patent-extension-trulicity	9/18/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/18/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125469	3301	365								1		
204760	Movantik	naloxegol	44T7335BKE	Oncology	small molecule	NDA	11/21/2007		November 21, 2007. The applicant claims October 22, 2007, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 21, 2007, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2018/02/16/2018-03245/determination-of-regulatory-review-period-for-purposes-of-patent-extension-movantik	9/16/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/16/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204760	2491	365										
125514	Keytruda	pembrolizumab	DPT0O3T46P	Oncology	antibody	BLA	1/7/2011		January 7, 2011. The applicant claims January 8, 2011, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 7, 2011, which was the first date after FDA receipt of the IND that the investigational studies were allowed to proceed.	https://www.federalregister.gov/documents/2018/01/31/2018-01890/determination-of-regulatory-review-period-for-purposes-of-patent-extension-keytruda	2/27/2014	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/4/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125514	1336	189	1	1		1	1	1				
205494	Cerdelga	eliglustat	DR40J4WA67	Endocrinology	small molecule	NDA	2/1/2004		February 1, 2004. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on February 1, 2004.	https://www.federalregister.gov/documents/2016/11/22/2016-28045/determination-of-regulatory-review-period-for-purposes-of-patent-extension-cerdelga	9/20/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/19/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205494	3852	333		1			1					

App	Product	NME ingredients	unii	Therapeutic Class	Molecule Type	App Type	IND date	IND date note	indDateComment	IND date ref	App submitted date	App submitted date ref	App approval date	App ref	Days in clinical development	Days in review	First	Orphan	Fast track	Break-through	Priority	Acceler-ated	Non-first cycle	Black box	Diagnostic imaging	Animal rule
125499	Plegridy	peginterferon beta-1a	I8309403R0	Neurology	protein	BLA	5/23/2007		May 23, 2007. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 23, 2007.	https://www.federalregister.gov/documents/2016/10/19/2016-25222/determination-of-regulatory-review-period-for-purposes-of-patent-extension-plegridy	5/16/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/15/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125499	2641	456										
204569	Belsomra	suvorexant	081L192FO9	Neurology	small molecule	NDA	5/7/2008		May 7, 2008. The applicant claims May 10, 2008, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 7, 2008, which was the date FDA notified the applicant that the IND studies may proceed.	https://www.federalregister.gov/documents/2018/02/12/2018-02763/determination-of-regulatory-review-period-for-purposes-of-patent-extension-belsomra	8/30/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/13/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204569	2289	713	1						1			
206334	Orbactiv	oritavancin	PUG62FRZ2E	Antibacterial	peptide	NDA	9/12/1996		September 12, 1996. The applicant claims September 11, 1996, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 12, 1996, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2016/06/17/2016-14353/determination-of-regulatory-review-period-for-purposes-of-patent-extension-orbactiv	12/6/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/6/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206334	6537	243					1					
204629	Jardiance	empagliflozin	HDC1R2M35U	Endocrinology	small molecule	NDA	5/11/2008		May 11, 2008. The applicant claims May 10, 2008, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 11, 2008, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2018/02/14/2018-02992/determination-of-regulatory-review-period-for-purposes-of-patent-extension-jardiance	3/5/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/1/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204629	2273	514							1			
203108	Striverdi Respimat	olodaterol	VD2YSN1AFD	Respiratory	small molecule	NDA	2/1/2005		https://www.federalregister.gov/documents/2017/12/26/2017-27710/determination-of-regulatory-review-period-for-purposes-of-patent-extension-striverdi-respimat February 28, 2007. FDA has verified the Boehringer Ingelheim Pharma GmbH & Co. KG claim that February 28, 2007, is the date the investigational new drug application (IND) became effective. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/203108Orig1s000MedR.pdf Discussion of Individual Studies/Clinical Trials 5.3.1 Trial 1222.3 (COPD) • Study dates: 12/15/2005-11/26/2006 https://www.mystudywindow.com/trial/completed/192795 BI 1222-0003 Single Dose Ranging Study of BI 1744 CL (Olodaterol) in Chronic Obstructive Pulmonary Disease Started: 01/12/2005 Ended: 01/11/2006 https://clinicaltrials.gov/ct2/show/NCT02171780 A Study to Assess Safety, Tolerability and Pharmacokinetics of Single Rising Inhaled Doses of BI 1744 CL in Healthy Male and Female Volunteers Study Start Date : February 2005	https://clinicaltrials.gov/ct2/show/NCT02171780	5/14/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/31/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203108	3467	808							1	1		
205858	Zydelig	idelalisib	YG57I8T5M0	Oncology	small molecule	NDA	5/30/2008		May 30, 2008. FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was on May 30, 2008. This is the same IND and the same date FDA determined as the beginning of the regulatory review period for ZYDELIG approved under NDA 205858. The regulatory review period for ZYDELIG approved under NDA 205858 is publishing in this issue of the	https://www.federalregister.gov/documents/2018/02/23/2018-03701/determination-of-regulatory-review-period-for-purposes-of-patent-extension-zydelig-new-drug	9/11/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/23/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205858	2245	315	1	1	1	1	1	1		1		
204427	Kerydin	tavaborole	K124A4EUQ3	Antifungal	small molecule	NDA	12/31/2005		December 31, 2005. FDA has verified the applicant's claim that December 31, 2005, is the date the investigational new drug application became effective.	https://www.federalregister.gov/documents/2018/02/14/2018-02993/determination-of-regulatory-review-period-for-purposes-of-patent-extension-kerydin	7/29/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/7/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204427	3110	343	1									
206256	Beleodaq	belinostat	F4H96P17NZ	Oncology	small molecule	NDA	12/16/2004		December 16, 2004. FDA has verified the Spectrum Pharmaceuticals, Inc. claim that December 16, 2004, is the date the investigational new drug application (NDA) became effective.	https://www.federalregister.gov/documents/2018/02/14/2018-03041/determination-of-regulatory-review-period-for-purposes-of-patent-extension-beleodaq	12/9/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/3/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=206256	3486	206		1	1		1	1				
205435	Sivextro	tedizolid phosphate	O7DRJ6R4DW	Antibacterial	small molecule	NDA	12/30/2007		December 30, 2007. The applicant claims December 27, 2007, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 30, 2007, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2017/12/26/2017-27684/determination-of-regulatory-review-period-for-purposes-of-patent-extension-sivextro	10/21/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/20/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205435	2364	242					1					
203567	Jublia	efinaconazole	J82SB7FXWB	Antifungal	small molecule	NDA	7/14/2007		July 14, 2007. FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was on July 14, 2007.	https://www.federalregister.gov/documents/2018/02/08/2018-02522/determination-of-regulatory-review-period-for-purposes-of-patent-extension-jublia	7/26/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/6/2014	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/203567_jublia_toc.cfm	2519	680							1			
21883	Dalvance	dalbavancin	808UI9MS5K	Antibacterial	peptide	NDA	8/13/2000		August 13, 2000. The applicant claims August 11, 2000, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 13, 2000, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2018/02/12/2018-02768/determination-of-regulatory-review-period-for-purposes-of-patent-extension-dalvance	12/21/2004	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/23/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021883	5031	3440			1		1		1			
125476	Entyvio	vedolizumab	9RV78Q2002	Gastroenterology	antibody	BLA	7/8/2000		https://www.federalregister.gov/documents/2016/09/16/2016-22344/determination-of-regulatory-review-period-for-purposes-of-patent-extension-entyvio July 8, 2000. The applicant claims August 18, 2000, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 8, 2000, which was 30 days after FDA receipt of the IND. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125476Orig1s000MedR.pdf Clinical development of vedolizumab began in 1998, and IND 009,125 was opened in June 2000 to initiate clinical development in the United States. 20 Sep 2000, Phase Change - I, Phase-I clinical trials for Ulcerative colitis in USA	https://www.federalregister.gov/documents/2016/09/16/2016-22344/determination-of-regulatory-review-period-for-purposes-of-patent-extension-entyvio	6/20/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/20/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125476	5064	334			1		1					
204886	Zontivity	vorapaxar	ZCE93644N2	Cardiology	small molecule	NDA	1/16/2005		January 16, 2005. FDA has verified the Merck Sharp & Dohme Corp. claim that January 16, 2005, is the date the investigational new drug application became effective.	https://www.federalregister.gov/documents/2018/02/15/2018-03170/determination-of-regulatory-review-period-for-purposes-of-patent-extension-zontivity	5/10/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/8/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204886	3399	363	1		1					1		
205755	Zykadia	ceritinib	K418KG2GET	Oncology	small molecule	NDA	11/7/2010		November 7, 2010. FDA has verified the applicants' claims that November 7, 2010, is the date the investigational new drug application became effective.	https://www.federalregister.gov/documents/2017/12/26/2017-27745/determination-of-regulatory-review-period-for-purposes-of-patent-extension-zykadia	12/24/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/29/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205755	1269	126		1		1	1	1				
125496	Sylvant	siltuximab	T4H8FMA7IM	Oncology	antibody	BLA	8/1/1998		January 21, 2004. The applicant claims January 8, 2004, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 21, 2004, which was 30 days after FDA receipt of the IND. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125496Orig1s000MedR.pdf 12/22/2003 Sponsor submits IND 11461 for CNTO 328 https://www.clinicaltrials.gov/ct2/show/NCT00265135 Study Start Date : August 2003. https://www.nature.com/articles/6605872 An earlier formulation of siltuximab was evaluated in a phase I, dose-ranging study of 10, 20, or 40 mg daily infusions administered in two 2-week cycles to 12 patients with multiple myeloma. This study demonstrated biological activity (van Zaanen et al, August 1998).	https://www.nature.com/articles/6605872	8/30/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/23/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125496	5744	236	1	1			1					
125477	Cyramza	ramucirumab	D99YVK4L0X	Oncology	antibody	BLA	9/1/2004		September 1, 2004. FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was on September 1, 2004.	https://www.federalregister.gov/documents/2016/04/15/2016-08692/determination-of-regulatory-review-period-for-purposes-of-patent-extension-cyramza	8/23/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/21/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125477	3519	241		1	1		1			1		
125431	Tanzeum	albiglutide	5E7U48495E	Endocrinology	peptide	BLA	1/15/2006		January 15, 2006. FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was on January 15, 2006.	https://www.federalregister.gov/documents/2016/06/10/2016-13797/determination-of-regulatory-review-period-for-purposes-of-patent-extension-tanzeum	1/14/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/15/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125431	3012	456								1		
205437	Otezla	apremilast	UP7QBP99PN	Dermatology	small molecule	NDA	8/28/2004		August 28, 2004. FDA has verified the Celgene Corporation claim that August 28, 2004, is the date the investigational new drug application (IND) became effective.	https://www.federalregister.gov/documents/2016/06/01/2016-12829/determination-of-regulatory-review-period-for-purposes-of-patent-extension-otezla	3/21/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/21/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205437	3492	365	1									
204677	Neuraceq	florbetaben F 18	TLA7312TOI	Neurology	small molecule	NDA	10/1/2007		Florbetaben was developed by Bayer HealthCare under IND 78,868. 12/19/2007 Pre-IND teleconference. ... 7.1.2 Overseas Phase I study (A02 study, CTD 5.3.3.1.3, October 2007-January 2008, reference material) An open-label, uncontrolled study to examine the in vivo distribution and systemic effective dose after administration of this drug in healthy foreign adults The study (target number of cases: 10 cases) was conducted at one overseas facility. https://www.pmda.go.jp/drugs/2016/P20161220002/400022000_22800AMX00725_A100_1.pdf	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/204677Orig1s000MedR.pdf	12/21/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/19/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204677	2361	453									1	
204684	Impavido	miltefosine	53EY29W7EC	Other Infectious disease	small molecule	NDA	NA	Ex-US clinical development predates IND	On March 8, 2010, the sponsor submitted IND 105,430 as a treatment IND with an openlabel protocol for the treatment of ML and potentially disseminated CL. It is registered in Germany as a topical drug to treat cutaneous cancers. As an oral agent, it is registered in Germany, Argentina, Colombia, Bolivia, Guatemala, Ecuador, Honduras, Peru, Paraguay, Mexico, Nepal, India, Pakistan and Bangladesh for the treatment of VL and CL. In March 2011, miltefosine was included in the WHO essential medicines list as an anti-leishmaniasis medicine3	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/204684Orig1s000MedR.pdf	4/19/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/19/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204684	NA	334	1	1	1		1					
125390	Myalept	metreleptin	TL60C27RLH	Endocrinology	peptide	BLA	5/2/1996		May 2, 1996. The applicants claim June 19, 2008, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the first IND effective date was May 2, 1996, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2016/09/23/2016-22935/determination-of-regulatory-review-period-for-purposes-of-patent-extension-myalept	3/27/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/24/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125390	6507	334	1	1	1		1			1		
203202	Northera	droxidopa	J7A92W69L7	Neurology	small molecule	NDA	NA	Ex-US clinical development predates IND	Droxidopa is a new molecular entity that not approved in the U.S.; however, it has been approved in Japan since 1989 for essentially the same indication now sought in the US. The drug was developed under Chelsea's IND 077248. Chelsea was first given this advice about the proposed clinical development program for droxidopa during the March 30, 2007, pre-IND meeting. The pre-IND meeting of May 1, 2007 included a lengthy discussion on the FDA's desire to see durability of effectiveness. Less than 6 months later, on September 20, 2007, Chelsea met with the Agency for an end-of-phase 2 meeting.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/203202Orig1s000MedR.pdf	9/28/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/18/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203202	NA	874	1	1	1		1	1	1	1		
125460	Vimizim	elosulfase alfa	ODJ69JZG85	Endocrinology	enzyme	BLA	12/28/2007		Effective on December 28, 2007, the applicant had initiated clinical development of BMN 110 under IND 101,234 in patients with Mucopolysaccharidosis type IVA (MPS IVA; Morquio A Syndrome), which is the proposed indication	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125460Orig1s000StatR.pdf	3/29/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/14/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125460	2240	322	1	1	1		1			1		
205677	Hetlioz	tasimelteon	SHS4PU80D9	Neurology	small molecule	NDA	3/16/1998		March 16, 1998. FDA has verified the Vanda Pharmaceuticals, Inc. claim that March 16, 1998, is the date the investigational new drug application (IND) became effective.	https://www.federalregister.gov/documents/2017/06/14/2017-12323/determination-of-regulatory-review-period-for-purposes-of-patent-extension-hetlioz	5/31/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/31/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205677	5800	245		1			1					
202293	Farxiga	dapagliflozin	1ULL0QJ8UC	Endocrinology	small molecule	NDA	12/21/2003		December 21, 2003. FDA has verified the AstraZeneca AB claim that the date the investigational new drug application became effective was on December 21, 2003.	https://www.federalregister.gov/documents/2018/02/07/2018-02418/determination-of-regulatory-review-period-for-purposes-of-patent-extension-farxiga	12/28/2010	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/8/2014	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202293	3671	1107							1			
203975	Anoro Ellipta	umeclidinium	GE2T1418SV	Respiratory	small molecule	NDA	8/14/2009		August 14, 2009. The applicant claims August 13, 2009, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 14, 2009, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2016/03/01/2016-04370/determination-of-regulatory-review-period-for-purposes-of-patent-extension-anoro-ellipta	12/18/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/18/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203975	1587	365										
204671	Sovaldi	sofosbuvir	WJ6CA3ZU8B	Antiviral	small molecule	NDA	3/30/2009		An Investigational New Drug application (IND) was submitted on November 13, 2009 by Pharmasset, Inc. After 30-day safety review, it was concluded that the Sponsor may proceed with the proposed clinical investigation under IND 106,739. Additional comments were provided to the Sponsor for consideration in regards to proposed clinical protocol/development plan in a letter signed December 10, 2009. https://www.pmda.go.jp/drugs/2015/P20150615003/230867000_22700AMX00691_K100_1.pdf Sample Collection Dates P7851-1101 30 Mar 2009 through 16 May 2009	https://www.pmda.go.jp/drugs/2015/P20150615003/230867000_22700AMX00691_K100_1.pdf	4/8/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/6/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204671	1712	242	1		1	1	1					
205123	Olysio	simeprevir	9WS5RD66HZ	Antiviral	small molecule	NDA	12/18/2007		https://www.federalregister.gov/documents/2016/05/31/2016-12708/determination-of-regulatory-review-period-for-purposes-of-patent-extension-olysio May 28, 2008. FDA has verified the Medivir AB and Janssen R&D Ireland claim that May 28, 2008, is the date the investigational new drug application (IND) became effective. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/205123Orig1s000ClinPharmR.pdf A blinded, randomized, placebo-controlled trial in genotype 1 hepatitis C-infected subjects to evaluate the efficacy, safety, tolerability, and pharmacokinetics of repeated doses of TMC435350, with or without peginterferon alpha-2a and ribavirin Trial Period 18 Dec 2007 to 26 Apr 2010	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/205123Orig1s000ClinPharmR.pdf	3/28/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/22/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205123	2166	239			1		1					
204153	Luzu	luliconazole	RE91AN4S8G	Antifungal	small molecule	NDA	9/27/2007		September 27, 2007. FDA has verified the Nihon Nohyaku Co., Ltd. claim that September 27, 2007, is the date the investigational new drug application (IND) became effective.	https://www.federalregister.gov/documents/2016/04/22/2016-09374/determination-of-regulatory-review-period-for-purposes-of-patent-extension-luzu	12/11/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/14/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204153	2240	338										
205552	Imbruvica	ibrutinib	1X70OSD4VX	Oncology	small molecule	NDA	10/7/2008		October 7, 2008. The applicant claims September 8, 2008, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 7, 2008, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2018/02/12/2018-02791/determination-of-regulatory-review-period-for-purposes-of-patent-extension-imbruvica	6/28/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/13/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205552	1863	138	1	1	1	1	1	1				
22416	Aptiom	eslicarbazepine acetate	BEA68ZVB2K	Neurology	small molecule	NDA	7/1/2000		https://www.federalregister.gov/documents/2016/04/12/2016-08334/determination-of-regulatory-review-period-for-purposes-of-patent-extension-aptiom December 20, 2006. FDA has verified the BIAL-PORTELA & CA, S.A. claim that December 20, 2006, is the date the investigational new drug application became effective. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/022416Orig1s000MedR.pdf The first-in-human study was study 2093-101. This study began in July of 2000 in London, UK. IND 67466 was opened in November 2006.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/022416Orig1s000MedR.pdf	3/30/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/8/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022416	4878	1684							1			

App	Product	NME ingredients	unii	Therapeutic Class	Molecule Type	App Type	IND date	IND date note	indDateComment	IND date ref	App submitted date	App submitted date ref	App approval date	App ref	Days in clinical development	Days in review	First	Orphan	Fast track	Break-through	Priority	Acceler-ated	Non-first cycle	Black box	Diagnostic imaging	Animal rule
125486	Gazyva	obinutuzumab	O43472U9X8	Oncology	antibody	BLA	9/1/2007		https://www.federalregister.gov/documents/2016/04/12/2016-08338/determination-of-regulatory-review-period-for-purposes-of-patent-extension-gazyva March 11, 2009. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on March 11, 2009. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/125486Orig1s000ClinPharmR.pdf NCA derived obinutuzumab serum PK exposure parameters in CLL patients following single and multiple dosing in phase 1 and 2 of trial BO20999 https://clinicaltrials.gov/ct2/show/NCT00517530 A Dose-Escalating Study of Obinutuzumab in Patients With B-lymphocyte Antigen (CD20+) Malignant Disease (GAUGUIN) Study Start Date : September 2007	https://clinicaltrials.gov/ct2/show/NCT00517530	4/22/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/1/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125486	2253	193		1		1	1			1		
203137	Vizamyl	flutemetamol F-18	L49M066S0O	Neurology	small molecule	NDA	10/24/2007		https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/203137Orig1s000PharmR.pdf Prior to the IND submission, several clinical trials and clinical research studies were conducted using Flutemetamol F 18 Injection in Finland, Europe, and in the United States under the aegis of the Radioactive Drug Research Committee(1) (RDRC) (The Pittsburgh Study, 2006). https://alzheimersanddementiajournal.com/article/S1552-5260(08)01054-6/fulltext P1-303: Phase I study of the 18F-labelled benzothiazole derivative [18F]AH110690 as a biomarker of Alzheimer's disease–related brain amyloidosis JULY 01, 2008 https://www.ema.europa.eu/en/documents/assessment-report/vizamyl-epar-public-assessment-report_en.pdf Initiation-End date 24 Oct 2007-05 Mar 2008	https://www.ema.europa.eu/en/documents/assessment-report/vizamyl-epar-public-assessment-report_en.pdf	10/26/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/25/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203137	2193	364									1	
204410	Opsumit	macitentan	Z9K9Y9WMVL	Hematology	small molecule	NDA	7/1/2004		https://www.federalregister.gov/documents/2016/03/10/2016-05389/determination-of-regulatory-review-period-for-purposes-of-patent-extension-opsumit July 3, 2008. The applicant claims July 2, 2008, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 3, 2008, which was 30 days after FDA receipt of the IND. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204410Orig1s000MedR.pdf See FDA reviewer's guide to NDA 204410 for complete submissions and communications with FDA regarding the development of macitentan under IND 77,258. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204410Orig1s000ClinPharmR.pdf Study: AC-055-101 Study Period: 2004 Title: Investigation of the single ascending dose tolerability, PK and PD of ACT-064992 in healthy male subjects https://link.springer.com/article/10.1007%2Fs00228-011-1043-2 Schleswig-Holstein Germany	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204410Orig1s000ClinPharmR.pdf	10/19/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/18/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204410	3396	364		1								
204819	Adempas	riociguat	RU3FE2Y4XI	Hematology	small molecule	NDA	3/22/2007		March 22, 2007. FDA has verified the Bayer Intellectual Property GmbH claim that March 22, 2007, is the date the investigational new drug application (IND) became effective.	https://www.federalregister.gov/documents/2016/04/12/2016-08337/determination-of-regulatory-review-period-for-purposes-of-patent-extension-adempas	2/8/2013	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/8/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204819	2392	242	1	1			1			1		
22247	Duavee	bazedoxifene	Q16TT9C5BK	Endocrinology	small molecule	NDA	3/15/1998		March 15, 1998. FDA has verified the Wyeth LLC claim that March 15, 1998, is the date the investigational new drug application (IND) became effective.	https://www.federalregister.gov/documents/2018/01/31/2018-01894/determination-of-regulatory-review-period-for-purposes-of-patent-extension-duavee	10/3/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/3/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022247	5681	365								1		
204447	Brintellix	vortioxetine	3O2K1S3WQV	Neurology	small molecule	NDA	5/4/2007		May 4, 2007. FDA has verified the H. Lundbeck A/S claim that May 4, 2007, is the date the investigational new drug application) became effective.	https://www.federalregister.gov/documents/2016/04/04/2016-07477/determination-of-regulatory-review-period-for-purposes-of-patent-extension-brintellix	10/2/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/30/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204447	2341	363								1		
204790	Tivicay	dolutegravir	DKO1W9H7M1	Antiviral	small molecule	NDA	10/24/2007		The Investigational New Drug application (IND 75382) for DTG was submitted on 24 October 2007.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204790Orig1s000MedR.pdf	12/17/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/12/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204790	2119	238			1		1					
201292	Gilotrif	afatinib	41UD74L59M	Oncology	small molecule	NDA	1/30/2004		January 30, 2004. FDA has verified the Boehringer Ingelheim Pharma Gmbh & Co., KG claim that January 30, 2004, is the date the investigational new drug application (IND) became effective.	https://www.federalregister.gov/documents/2018/02/12/2018-02767/determination-of-regulatory-review-period-for-purposes-of-patent-extension-gilotrif	11/15/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/12/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=201292	3451	239		1	1		1					
204114	Mekinist	trametinib	33E86K87QN	Oncology	small molecule	NDA	5/15/2008		May 15, 2008. FDA has verified the Japan Tobacco, Inc., claim that May 15, 2008, is the date the investigational new drug application became effective.	https://www.federalregister.gov/documents/2016/06/01/2016-12859/determination-of-regulatory-review-period-for-purposes-of-patent-extension-mekinist	8/3/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/29/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204114	1840	299	1	1	1							
202806	Tafinlar	dabrafenib	QGP4HA4G1B	Oncology	small molecule	NDA	7/24/2009		The Applicant submitted IND 105032 on June 26, 2009, and received notification from FDA that the first-in-human study (BRFI 12680) was allowed to proceed on July 24, 2009.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/202806Orig1s000MedR.pdf	7/30/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/29/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202806	1405	303		1	1							
203971	Xofigo	radium Ra 223 dichloride	RJ00KV3VTG	Oncology	small molecule	NDA	8/14/2001		https://www.federalregister.gov/documents/2016/06/21/2016-14551/determination-of-regulatory-review-period-for-purposes-of-patent-extension-xofigo January 19, 2008. Algeta ASA claims that February 21, 2008, is the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 19, 2008, which was 30 days after FDA receipt of the IND. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/203971Orig1s000MedR.pdf ATI BC-1 / 15522 Phase 1: Single Dose, Dose Escalation. Repeat dose in some subjects. https://www.clinicaltrials.gov/ct2/show/NCT01798108 Other Study ID Numbers: ATI-BC-1Actual Study Start Date : August 14, 2001	https://www.clinicaltrials.gov/ct2/show/NCT01798108	12/14/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/15/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203971	4292	152	1		1		1					
204275	Breo Ellipta	vilanterol	028LZY775B	Respiratory	small molecule	NDA	12/10/2007		December 10, 2007. The applicant claims June 26, 2008, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 10, 2007, which was 30 days after FDA receipt of the first IND.	https://www.federalregister.gov/documents/2016/02/22/2016-03551/determination-of-regulatory-review-period-for-purposes-of-patent-extension-breo-ellipta	7/12/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/10/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204275	1978	302										
204042	Invokana	canagliflozin	0SAC974Z85	Endocrinology	small molecule	NDA	11/15/2006		https://www.federalregister.gov/documents/2016/03/01/2016-04369/determination-of-regulatory-review-period-for-purposes-of-patent-extension-invokana May 25, 2007. FDA has verified the Mitsubishi Tanabe Pharma Corporation of Osaka, Japan claim that May 25, 2007, is the date the investigational new drug application became effective https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204042Orig1s000ClinPharmR.pdf single ascending doses of canagliflozin in Study NAP1001 https://www.pmda.go.jp/drugs/2014/P201400070/400315000_22600AMX00744_K105_1.pdf A First-in-Human Study to Evaluate Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single Escalating Oral Doses of JNJ-28431754 in Healthy Male Subjects NAP1001 November 15, 2006-April 27, 2007	https://www.pmda.go.jp/drugs/2014/P201400070/400315000_22600AMX00744_K105_1.pdf	5/31/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/29/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204042	2326	302	1									
204063	Tecfidera	dimethyl fumarate	FO2303MNI2	Neurology	small molecule	NDA	NA	Ex-US clinical development predates IND	https://www.federalregister.gov/documents/2017/10/05/2017-21435/determination-of-regulatory-review-period-for-purposes-of-patent-extension-tecfidera June 14, 2006. FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was on June 14, 2006. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204063Orig1s000MedR.pdf Dimethyl fumarate has not yet been approved by a regulatory agency although Fumaderm, a combination product containing dimethyl fumarate and other fumarate esters, has been approved in Germany for treatment of psoriasis since 1994. The first medical use of fumaric acid, as a topical formulation for psoriasis, was described in 1959 by Walter Schweckendiek, a German chemist, and was a topical formulation for psoriasis. The Swiss company Fumapharm eventually brought Fumaderm, an oral formulation of DMF (along with some monoesters) to market for psoriasis in Germany in 1994.	https://www.federalregister.gov/documents/2017/10/05/2017-21435/determination-of-regulatory-review-period-for-purposes-of-patent-extension-tecfidera	2/27/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/27/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204063	NA	394	1									
125462	BAT	equine botulinum neurotoxin A-G immune fab2	X5I2P7E9TY|30Y9N0SEBE|T95649SUV7|RJN8G983LQ|943578J0XG	Antibacterial	antibody	BLA	7/1/2006		Presubmission activities are documented in minutes from previous meetings. These occurred on 2012-06-13, 2011-05-27, 2010-07-13, 2009-12-10, and 2004-08-26. IND investigations were done under 6750 and 12052. BT-001: The primary objective was to evaluate the safety of NP-018 based upon clinical observations, adverse events (AEs) and laboratory assessments. The secondary objective was to assess the pharmacokinetics (PK) of the seven botulinum antitoxin serotypes contained in NP-018 following intravenous (IV) administration. [Source: Original BLA 125462/0; BT001-study-report-body, p. 2]	https://clinicaltrials.gov/ct2/show/NCT00360737	9/20/2012	https://wayback.archive-it.org/7993/20170723024133/https://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/UCM358262.pdf	3/22/2013	https://wayback.archive-it.org/7993/20170722071334/https://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/ucm345134.htm	2456	183		1			1					1
204781	Dotarem	gadoterate meglumine	L0ND3981AG	Neurology	small molecule	NDA	6/12/2002		A pre-IND meeting to discuss future filing was held on September 21, 2000 followed by an IND submission on June 12, 2002.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204781Orig1s000MedR.pdf	9/20/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/20/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204781	3934	181					1			1	1	
202207	Lymphoseek	technetium Tc 99m tilmanocept	8IHI69PQTC	Oncology	polymer	NDA	2/28/2001		February 28, 2001. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on February 28, 2001.	https://www.federalregister.gov/documents/2018/02/22/2018-03610/determination-of-regulatory-review-period-for-purposes-of-patent-extension-lymphoseek	8/10/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/13/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202207	4396	581							1		1	
203505	Osphena	ospemifene	B0P231ILBK	Neurology	small molecule	NDA	5/7/2003		May 7, 2003. FDA has verified the Hormos Medical Ltd. claim that May 7, 2003, is	https://www.federalregister.gov/documents/2016/06/01/2016-12823/determination-of-regulatory-review-period-for-purposes-of-patent-extension-osphena	4/26/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/26/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203505	3583	306										
125427	Kadcyla	ado-trastuzumab emtansine	SE2KH7T06F	Oncology	antibody	BLA	1/18/2006		January 18, 2006. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 18, 2006.	https://www.federalregister.gov/documents/2015/12/28/2015-32475/determination-of-regulatory-review-period-for-purposes-of-patent-extension-kadcyla	8/27/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/22/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125427	2592	179	1		1		1			1		
204026	Pomalyst	pomalidomide	D2UX06XLB5	Oncology	small molecule	NDA	12/9/2002		December 9, 2002. The applicant claims December 14, 2002, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 9, 2002, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.	https://www.federalregister.gov/documents/2016/06/10/2016-13796/determination-of-regulatory-review-period-for-purposes-of-patent-extension-pomalyst	4/10/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/8/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204026	3714	304		1	1			1		1		
203568	Kynamro	mipomersen sodium	18EAY4870E	Endocrinology	oligo	NDA	12/18/2005		December 18, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 18, 2005.	https://www.federalregister.gov/documents/2015/04/24/2015-09522/determination-of-regulatory-review-period-for-purposes-of-patent-extension-kynamro	3/29/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/29/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203568	2599	306	1	1						1		
22271	Nesina	alogliptin	JHC049LO86	Endocrinology	small molecule	NDA	10/20/2004		October 20, 2004. The applicant claims October 19, 2004, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 20, 2004, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2015/05/04/2015-10337/determination-of-regulatory-review-period-for-purposes-of-patent-extension-nesina	12/27/2007	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/25/2013	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022271	3019	1856							1			
202292	Fulyzaq	crofelemer	PY79D6C8RX	Other Infectious disease	polymer	NDA	9/11/1991		September 11, 1991. The applicant claims August 14, 1991, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 11, 1991, which was 30 days after FDA receipt of the first IND from the sponsor for this new drug.	https://www.federalregister.gov/documents/2015/12/10/2015-31097/determination-of-regulatory-review-period-for-purposes-of-patent-extension-fulyzaq	12/5/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/31/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202292	7782	392	1		1		1					
202155	Eliquis	apixaban	3Z9Y7UWC1J	Cardiology	small molecule	NDA	11/28/2002		November 28, 2002. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 28, 2002.	https://www.federalregister.gov/documents/2015/12/10/2015-31096/determination-of-regulatory-review-period-for-purposes-of-patent-extension-eliquis	9/28/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/28/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202155	3683	457			1		1		1			
204384	Sirturo	bedaquiline	78846I289Y	Respiratory	small molecule	NDA	12/9/2006		December 9, 2006. The applicant claims November 9, 2006, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 9, 2006, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2015/12/10/2015-31098/determination-of-regulatory-review-period-for-purposes-of-patent-extension-sirturo	6/29/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/28/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=204384	2211	182	1	1	1		1	1				
203441	Gattex	teduglutide	7M19191IKG	Gastroenterology	peptide	NDA	5/27/1999		May 27, 1999. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 27, 1999.	https://www.federalregister.gov/documents/2015/05/07/2015-11000/determination-of-regulatory-review-period-for-purposes-of-patent-extension-gattex	11/30/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/21/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203441	4957	387	1	1								
203858	Juxtapid	lomitapide	82KUB0583F	Endocrinology	small molecule	NDA	7/18/1996		July 18, 1996. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 18, 1996.	https://www.federalregister.gov/documents/2015/04/06/2015-07809/determination-of-regulatory-review-period-for-purposes-of-patent-extension-juxtapid	2/29/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/21/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203858	6000	296	1	1						1		
125349	raxibacumab	raxibacumab	794PGL549S	Antibacterial	antibody	BLA	6/22/2003		June 22, 2003. The applicant claims July 18, 2003, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 22, 2003, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2015/12/15/2015-31400/determination-of-regulatory-review-period-for-purposes-of-patent-extension-raxibacumab	5/14/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/14/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125349	3463	1310	1	1	1		1		1			1
200677	Signifor	pasireotide	98H1T17066	Endocrinology	peptide	NDA	7/17/2003		July 17, 2003. The applicant claims July 16, 2003, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 17, 2003, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2015/05/07/2015-10994/determination-of-regulatory-review-period-for-purposes-of-patent-extension-signifor	2/17/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/14/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=200677	3438	301	1	1								
203469	Iclusig	ponatinib	4340891KFS	Oncology	small molecule	NDA	11/21/2007		Pre-IND meeting occurred on 4 September 2007, which was followed by the IND submission (IND 78375) on 21 November 2007.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/203469Orig1s000MedR.pdf	9/27/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	12/14/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203469	1850	78		1	1		1	1				
203756	Cometriq	cabozantinib	1C39JW444G	Oncology	small molecule	NDA	7/13/2005		July 13, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 13, 2005.	https://www.federalregister.gov/documents/2015/04/22/2015-09302/determination-of-regulatory-review-period-for-purposes-of-patent-extension-cometriq	5/29/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/29/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203756	2696	184		1	1		1			1		

App	Product	NME ingredients	unii	Therapeutic Class	Molecule Type	App Type	IND date	IND date note	indDateComment	IND date ref	App submitted date	App submitted date ref	App approval date	App ref	Days in clinical development	Days in review	First	Orphan	Fast track	Break-through	Priority	Acceler-ated	Non-first cycle	Black box	Diagnostic imaging	Animal rule
203214	Xeljanz	tofacitinib	87LA6FU830	Rheumatology	small molecule	NDA	1/18/2002		January 18, 2002. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 18, 2002.	https://www.federalregister.gov/documents/2015/06/12/2015-14433/determination-of-regulatory-review-period-for-purposes-of-patent-extension-xeljanz	10/21/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/6/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203214	3945	382								1		
203585	Synribo	omacetaxine mepesuccinate	6FG8041S5B	Oncology	small molecule	NDA	5/17/2001		May 17, 2001. The applicant claims May 18, 2001, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 17, 2001, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2015/05/07/2015-11004/determination-of-regulatory-review-period-for-purposes-of-patent-extension-synribo	3/30/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/26/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203585	4180	210	1	1	1			1				
202834	Fycompa	perampanel	H821664NPK	Neurology	small molecule	NDA	11/7/2003		November 7, 2003. FDA has verified the Eisai R&D Management Co., Ltd. claim that November 7, 2003, is the date the investigational new drug application became effective.	https://www.federalregister.gov/documents/2016/09/23/2016-22933/determination-of-regulatory-review-period-for-purposes-of-patent-extension-fycompa	12/22/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/22/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202834	3272	305	1							1		
125422	Jetrea	ocriplasmin	7V6HE3DM5A	Opthamology	peptide	BLA	11/9/2006		November 9, 2006. The applicant claims November 11, 2006, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 9, 2006, when the investigational studies were allowed to proceed.	https://www.federalregister.gov/documents/2015/12/23/2015-32247/determination-of-regulatory-review-period-for-purposes-of-patent-extension-jetrea	4/17/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/17/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125422	2169	183	1				1					
203085	Stivarga	regorafenib	24T2A1DOYB	Oncology	small molecule	NDA	8/18/2006		August 18, 2006. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 18, 2006.	https://www.federalregister.gov/documents/2015/05/22/2015-12577/determination-of-regulatory-review-period-for-purposes-of-patent-extension-stivarga	4/27/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/27/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203085	2232	153			1		1			1		
203155	Choline C 11 Injection	choline C-11	M4AS4XGD4Q	Oncology	small molecule	NDA	NA	Original IND submission date not provided	The Mayo Clinic has applied for an NDA under the Section 505(b)(2) pathway of the 1984 Federal Food, Drug and Cosmetic Act which means that the application contains full reports of investigations of safety and effectiveness but at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Choline C11 Injection is one of the positron emission tomography (PET) drugs that has been in clinical use over the past many years, consistent with the provisions of the Food and Drug Administration Modernization Act of 1997 (The Act).	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/203155Orig1s000SumR.pdf	12/12/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/12/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203155	NA	275					1				1	
202992	Aubagio	teriflunomide	1C058IKG3B	Neurology	small molecule	NDA	8/27/2004		August 27, 2004. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 27, 2004.	https://www.federalregister.gov/documents/2015/04/15/2015-08615/determination-of-regulatory-review-period-for-purposes-of-patent-extension-aubagio-patent-no-5679709	8/12/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/12/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202992	2938	397								1		
203341	Bosulif	bosutinib	5018V4AEZ0	Oncology	small molecule	NDA	5/19/2004		May 19, 2004. The applicant claims May 16, 2004, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 19, 2004, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2015/05/04/2015-10333/determination-of-regulatory-review-period-for-purposes-of-patent-extension-bosulif	11/17/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/4/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203341	3030	292		1								
203415	Xtandi	enzalutamide	93T0T9GKNU	Oncology	small molecule	NDA	6/29/2007		June 29, 2007. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 29, 2007.	https://www.federalregister.gov/documents/2015/12/18/2015-31824/determination-of-regulatory-review-period-for-purposes-of-patent-extension-xtandi	5/22/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/31/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203415	1890	101			1		1					
202811	Linzess	linaclotide	N0TXR0XR5X	Gastroenterology	peptide	NDA	10/30/2004		October 30, 2004. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 30, 2004.	https://www.federalregister.gov/documents/2014/05/23/2014-11926/determination-of-regulatory-review-period-for-purposes-of-patent-extension-linzess	8/9/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/30/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202811	2861	387	1							1		
203100	Stribild	elvitegravir| cobicistat	4GDQ854U53| LW2E03M5PG	Antiviral	small molecule	NDA	4/18/2005		IND 72177 for EVG tablets was opened on April 18, 2005. From the onset, the development of EVG (boosted with RTV) was intended for a treatmentexperienced indication. However, agreement on a noninferiority margin for the pivotal Phase 3 trials proved challenging and enrollment in the trials lagged due decreasing numbers of eligible participants. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/203094Orig1Orig2s000MedR.pdf IND 101283 for COBI (GS-9350) tablets was opened on April 10, 2008, following pre-IND consultation obtained on February 6, 2008. In both submissions, the Applicant indicated its intention to initially pursue registration of GS-9350 as part of a fixed-dose combination (FDC) tablet including EVG/FTC/TDF as a complete regimen for HIV-1 infected treatment-naive adults.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/203094Orig1Orig2s000MedR.pdf	10/27/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/27/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203100	2688	305			1					1		
125418	Zaltrap	ziv-aflibercept	15C2VL427D	Oncology	antibody	BLA	8/2/2001		IND 9948 was submitted by Regeneron Pharmaceuticals on August 2, 2001 for the clinical development program of xxx_aflibercept for the treatment of patients ...	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/125418Orig1s000SumR.pdf	2/3/2012	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/3/2012	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/125418_zaltrap_toc.cfm	4019	182					1			1		
202450	Tudorza Pressair	aclidinium bromide	UQW7UF9N91	Respiratory	small molecule	NDA	12/24/2003		December 24, 2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 24, 2003.	https://www.federalregister.gov/documents/2015/05/04/2015-10336/determination-of-regulatory-review-period-for-purposes-of-patent-extension-tudorza-pressair	6/23/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/23/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202450	3134	396										
202714	Kyprolis	carfilzomib	72X6E3J5AR	Oncology	small molecule	NDA	7/14/2005		July 14, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 14, 2005.	https://www.federalregister.gov/documents/2014/05/15/2014-11175/determination-of-regulatory-review-period-for-purposes-of-patent-extension-kyprolis	9/27/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/20/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202714	2563	297		1	1			1				
202535	Prepopik	sodium picosulfate	LR57574HN8	Gastroenterology	small molecule	NDA	NA	Ex-US clinical development predates IND	The combination of sodium picosulfate with magnesium oxide and citric acid that is the subject of this application is currently approved for use for colon cleansing in 33 countries around the world. The product, under the trade names Picolax, PicoSalax, Pico-Salax, or Picoprep, is currently marketed in Canada, Australia and United Kingdom. A Type B, Pre-Investigational New Drug (IND) Application meeting was held on 16 April 2009 to obtain assistance from the Agency regarding the development program for PICOPREP. The development program for Prepopik occurred under IND 101738. IND 101738 was submitted on February 22, 2010.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202535Orig1s000PharmR.pdf	9/16/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/16/2012	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202535_prepopik_toc.cfm	NA	304										
202611	Myrbetriq	mirabegron	MVR3JL3B2V	Neurology	small molecule	NDA	6/9/2006		June 9, 2006. The applicant claims May 10, 2006, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 9, 2006, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2014/05/28/2014-12292/determination-of-regulatory-review-period-for-purposes-of-patent-extension-myrbetriq	8/29/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/28/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202611	2211	304	1									
22529	Belviq	lorcaserin hydrochloride	0QJF08GDPE	Endocrinology	small molecule	NDA	6/23/2004		June 23, 2004. FDA has verified the Arena Pharmaceuticals, Inc. claim that June 23, 2004, is the date the investigational new drug application became effective.	https://www.federalregister.gov/documents/2016/09/23/2016-22937/determination-of-regulatory-review-period-for-purposes-of-patent-extension-belviq	12/22/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/27/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022529	2926	918	1						1			
125409	Perjeta	pertuzumab	K16AIQ8CTM	Oncology	antibody	BLA	9/11/2001		September 11, 2001. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 11, 2001.	https://www.federalregister.gov/documents/2014/05/19/2014-11515/determination-of-regulatory-review-period-for-purposes-of-patent-extension-perjeta	12/8/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/8/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125409	3923	183					1			1		
22458	Elelyso	taliglucerase alfa	0R4NLX88O4	Endocrinology	enzyme	BLA	7/16/2005		July 16, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 16, 2005.	https://www.federalregister.gov/documents/2014/05/19/2014-11516/determination-of-regulatory-review-period-for-purposes-of-patent-extension-elelyso	4/26/2010	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/1/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022458	2481	736		1	1				1			
202276	Stendra	avanafil	DR5S136IVO	Neurology	small molecule	NDA	1/2/2002		January 2, 2002. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 2, 2002.	https://www.federalregister.gov/documents/2014/06/10/2014-13444/determination-of-regulatory-review-period-for-purposes-of-patent-extension-stendra	6/29/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/27/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202276	3768	303										
202008	Amyvid	florbetapir F 18	6W15Z5R0RU	Neurology	small molecule	NDA	3/6/2008		Regulatory History: 1. Exploratory IND 76-852 was filed on 01/08/2007 (withdrawn on 02/14/2008) 2. Pre-IND and then IND 79-511 was filed on 03/06/2008	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202008Orig1s000MedR.pdf	9/17/2010	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/6/2012	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202008_Florbetapir_Orig1s000TOC.cfm	1492	567	1				1		1		1	
202799	Omontys	peginesatide	JX56W9N61Q	Hematology	peptide	NDA	8/1/2004		https://www.federalregister.gov/documents/2014/05/20/2014-11523/determination-of-regulatory-review-period-for-purposes-of-patent-extension-omontys April 27, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 27, 2005. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202799Orig1s000ClinPharmR.pdf In a phase 1 dose escalation study (AFX01-0401, N=28) in healthy volunteers ... https://clinicaltrials.gov/ct2/show/NCT00097747 Study Start Date : August 2004	https://clinicaltrials.gov/ct2/show/NCT00097747	5/27/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/27/2012	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202799_Omontys_Orig1s000TOC.cfm	2795	305								1		
21746	Surfaxin	sinapultide	040X3AX99T	Respiratory	peptide	NDA	9/5/1992		September 5, 1992. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 5, 1992.	https://www.federalregister.gov/documents/2014/05/13/2014-10904/determination-of-regulatory-review-period-for-purposes-of-patent-extension-surfaxin	4/13/2004	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/6/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021746	7122	2884			1				1			
202514	Zioptan	tafluprost	1O6WQ6T7G3	Opthamology	small molecule	NDA	6/28/2001		June 28, 2001. The applicant claims June 24, 2001, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 28, 2001, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2014/05/19/2014-11517/determination-of-regulatory-review-period-for-purposes-of-patent-extension-zioptan	1/7/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/10/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202514	3879	399										
203188	Kalydeco	ivacaftor	1Y740ILL1Z	Respiratory	small molecule	NDA	4/13/2006		April 13, 2006. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 13, 2006.	https://www.federalregister.gov/documents/2014/05/30/2014-12561/determination-of-regulatory-review-period-for-purposes-of-patent-extension-kalydeco	10/18/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/31/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203188	2119	105	1	1	1		1					
203388	Erivedge	vismodegib	25X868M3DS	Oncology	small molecule	NDA	11/3/2006		The applicant submitted the original IND for vismodegib on September 29, 2006 (received October 2, 2006). FDA issued a may proceed letter for IND 74,573 on November 3, 2006.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/203388Orig1s000MedRpdf.pdf	9/8/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/30/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203388	1914	144	1				1			1		
202324	Inlyta	axitinib	C9LVQ0YUXG	Oncology	small molecule	NDA	12/13/2001		December 13, 2001. The applicant claims December 14, 2001, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 13, 2001, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2014/05/23/2014-11925/determination-of-regulatory-review-period-for-purposes-of-patent-extension-inlyta	4/14/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/27/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202324	3697	288			1							
202833	Picato	ingenol mebutate	7686S50JAH	Dermatology	small molecule	NDA	7/28/2004		July 28, 2004. The applicant claims July 9, 2004, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 28, 2004, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2014/05/20/2014-11521/determination-of-regulatory-review-period-for-purposes-of-patent-extension-picato	3/25/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/23/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202833	2735	304	1									
125327	Voraxaze	glucarpidase	2GFP9BJD79	Hematology	enzyme	BLA	8/7/1992		IND 4663, sponsored by the National Cancer Institute (NCI), was submitted August 7, 1992 and inactivated on October 16, 2006. IND 11630, sponsored by the NCI, was subinitted Mai·ch 30, 2004 and received March 31, 2004. On April 8, 2004, FDA requested, and NCI agreed to provide a protocol for, collection of complete phaimacokinetic data in a minimum 12 patients at selected sites receiving the Protherics-manufactured product up to 48 hours after dosing. Study PR00I-CLN-1pt006 (also refened to as the NCI PD study) conducted under this IND, began emollment in July 2004. By the time of the proposed data cut-off date of November 4, 2005, 68 patients had been emolled, with at least 27 patients having methotrexate concentrations dete1mined by HPLC and 27 patients with complete (n=13) or paiiial (n=14) assessment for anti-glucaipidase antibodies. This IND was inactivated on May 11, 2007, subsequent to the removal of the clinical hold for the treatment protocol for glucaipidase under IND 11557. IND 11557 was subinitted Feb. 18, 2004 by Protherics, Inc.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/125327Orig1s000SumR.pdf	7/18/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/17/2012	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125327	7102	183	1	1	1		1					
125359	Erwinaze	asparaginase Erwinia chrysanthemi	D733ET3F9O	Oncology	enzyme	BLA	4/1/1968		Erwinia L-asparaginase has been available in the US since 1968 under Investigational New Drug (IND) 290 originally held by Ipsen Ltd. In February 2006 Ipsen Ltd transferred all rights and responsibilities of IND 290 to Orphan Pharmaceuticals International (OPi) SA (subsequently EUSA Pharma (US)). Erwinia L-asparaginase (Crisantaspase, Erwinase) is available in some countries in Europe and in Canada. April 1968 / Ipsen Ltd. original sponsor IND 290 submitted	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/125359Orig1s000MedR.pdf	11/1/2010	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/18/2011	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/125359_erwinaze_toc.cfm	15936	382		1	1		1					
125387	Eylea	aflibercept	15C2VL427D	Oncology	protein	BLA	6/15/2005		June 15, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 15, 2005.	https://www.federalregister.gov/documents/2014/04/02/2014-07333/determination-of-regulatory-review-period-for-purposes-of-patent-extension-eylea	2/18/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/18/2011	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/125387s000TOC.cfm	2347	273					1					
202192	Jakafi	ruxolitinib	82S8X8XX8H	Rheumatology	small molecule	NDA	3/30/2007		03/30/07 Submission of IND 77456 by Incyte	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/202192Orig1s000MedR.pdf	6/3/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/16/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202192	1692	166	1	1	1		1					
125397	Hemacord	human cord blood hematopoietic progenitor cell	XU53VK93MC	Hematology	cell	BLA	5/29/1996		4/26/1996 IND 6637 submitted; allowed to proceed 5/29/1996	https://www.fda.gov/media/82073/download	1/10/2011	https://www.fda.gov/media/82073/download	11/10/2011	https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/hemacord-hpc-cord-blood	5643	304										

App	Product	NME ingredients	unii	Therapeutic Class	Molecule Type	App Type	IND date	IND date note	indDateComment	IND date ref	App submitted date	App submitted date ref	App approval date	App ref	Days in clinical development	Days in review	First	Orphan	Fast track	Break-through	Priority	Acceler-ated	Non-first cycle	Black box	Diagnostic imaging	Animal rule
202067	Onfi	clobazam	2MRO291B4U	Neurology	small molecule	NDA	NA	Ex-US clinical development predates IND	Clobazam was first approved in 1970 in Australia (international birth date) and has also been approved for the treatment of anxiety and/or the adjunctive treatment of epilepsy in over 100 countries. In the U.S., an IND was filed on 25 May 2005 by Lundbeck Inc. (Lundbeck) (formerly Ovation Pharmaceuticals); the company was notified by the Division of Neurology Products on 24 June 2005 that clinical studies with clobazam under IND 70,125 could proceed. A Type B, End of Phase 2 (EOP2) meeting was held with the Division on 09 May 2007 to discuss the results obtained from the completed Phase 2 study, OV -1002, and to discuss planning for the pivotal Phase 3 study (OV-1012) and preparation for filing a U.S. NDA.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/202067Orig1s000MedR.pdf	12/23/2010	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/21/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202067	NA	302		1								
21825	Ferriprox	deferiprone	2BTY8KH53L	Endocrinology	small molecule	NDA	NA	Ex-US clinical development predates IND	The drug was first administered to humans in 1987, was approved in the European Union in 1999 and currently is approved in 61 countries, mostly for the indication of the treatment of iron overload in patients with thalassemia major when deferoxamine therapy is contraindicated or inadequate. The U.S. IND for deferiprone (IND 45724) was opened 7/15/1994.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/021825Orig1s000MedR.pdf	1/30/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/14/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021825	NA	987		1	1			1	1	1		
202570	Xalkori	crizotinib	53AH36668S	Oncology	small molecule	NDA	1/12/2006		January 12, 2006. The applicant claims January 21, 2006, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 12, 2006, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2013/01/31/2013-02085/determination-of-regulatory-review-period-for-purposes-of-patent-extension-xalkori	3/30/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/26/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202570	2052	149	1	1	1		1	1				
22150	Firazyr	icatibant	7PG89G35Q7	Hematology	small molecule	NDA	5/12/2004		May 12, 2004. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 12, 2004.	https://www.federalregister.gov/documents/2014/04/02/2014-07331/determination-of-regulatory-review-period-for-purposes-of-patent-extension-firazyr	10/26/2007	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/25/2011	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/022150_firazyr_toc.cfm	2661	1399	1	1	1		1		1			
125388	Adcetris	brentuximab vedotin	7XL5ISS668	Oncology	antibody	BLA	6/27/2006		Seattle Genetics, Inc. opened IND 71634 on 27 June 2006.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/125388Orig1s000MedR.pdf	2/28/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/19/2011	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/125388_adcetris_toc.cfm	1879	172	1	1	1		1	1				
202429	Zelboraf	vemurafenib	207SMY3FQT	Oncology	small molecule	NDA	9/1/2006		IND-73620 Submission Sept. 2006 The IND named PLX4032, claimed as a selective inhibitor of BRAF kinase V600E mutant and intended to be investigated in patients with tumors containing the point mutation, including melanoma. The Phase 1 protocol	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/202429Orig1s000MedR.pdf	4/28/2011	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/17/2011	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/202429s000TOC.cfm	1811	111	1	1	1		1					
125335	Anascorp	scorpion (centruroides) immune fab2 antivenin (equine)	DDA050FCEA	Emergency Medicine	antibody	BLA	NA	Original IND submission date not provided	Study AL-99/02 was conducted in 1999 and was not intended to support efficacy for the BLA STN 125335/0. This study was not conducted under the current IND (BB-IND -(b)(4)-). Only the Anascorp results of this study were presented in the BLA (see Volume 1.15, page 002, CSR XE-C-05), for completeness of data collected and to show that based on these results as well as post-approval efficacy results in Mexico, the Sponsor was encouraged to open an IND to begin the study of Anascorp in the United States. The IND under which clinical data were obtained is BB-IND -(b)(4)-. An approved therapy for the treatment of scorpion envenomation is currently not available in the US. The only previously available U.S. scorpion antivenom, a goat whole-IgG immunoglobulin preparation provided since 1965 by Arizona State University under the State of Arizona, ceased production in 2000.	https://web.archive.org/web/20170723145859/https://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/UCM270159.pdf	1/22/2009	https://wayback.archive-it.org/7993/20170723030046/https://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/UCM270465.pdf	8/3/2011	https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/anascorp	NA	923		1			1		1			
22433	Brilinta	ticagrelor	GLH0314RVC	Cardiology	small molecule	NDA	5/29/2003		May 29, 2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 29, 2003.	https://www.federalregister.gov/documents/2014/04/30/2014-09772/determination-of-regulatory-review-period-for-purposes-of-patent-extension-brilinta	11/16/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/20/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022433	2974	611							1	1		
22383	Arcapta	indacaterol	8OR09251MQ	Respiratory	small molecule	NDA	1/9/2003		January 9, 2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 9, 2003.	https://www.federalregister.gov/documents/2014/06/12/2014-13638/determination-of-regulatory-review-period-for-purposes-of-patent-extension-arcapta-neohaler	12/18/2008	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/1/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022383	3095	925							1	1		
22406	Xarelto	rivaroxaban	9NDF7JZ4M3	Cardiology	small molecule	NDA	6/29/2002		June 29, 2002. The applicant claims June 30, 2002, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 29, 2002, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2014/05/29/2014-12349/determination-of-regulatory-review-period-for-purposes-of-patent-extension-xarelto	7/28/2008	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/1/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022406	3289	1068							1	1		
125288	Nulojix	belatacept	E3B2GI648A	Immunology	protein	BLA	3/13/1999		March 13, 1999. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on March 13, 1999.	https://www.federalregister.gov/documents/2014/03/31/2014-07060/determination-of-regulatory-review-period-for-purposes-of-patent-extension-nulojix	7/1/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/15/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125288	4477	714	1	1	1				1	1		
22345	Potiga	ezogabine	12G01I6BBU	Neurology	small molecule	NDA	9/12/1997		September 12, 1997. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 12, 1997.	https://www.federalregister.gov/documents/2014/04/02/2014-07334/determination-of-regulatory-review-period-for-purposes-of-patent-extension-potiga	10/30/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/10/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022345	5019	588							1			
201699	Dificid	fidaxomicin	Z5N076G8YQ	Antibacterial	small molecule	NDA	8/20/2003		The IND (number 64,435) application for fidaxomicin was filed on August 20, 2003.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/201699Orig1s000StatR.pdf	11/30/2010	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/27/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=201699	2837	178			1		1					
201917	Incivek	telaprevir	655M5O3W0U	Antiviral	small molecule	NDA	11/29/2005		November 29, 2005. The applicant claims December 2, 2005, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 29, 2005, when the IND sponsor was notified that the proposed clinical studies may proceed.	https://www.federalregister.gov/documents/2014/05/20/2014-11525/determination-of-regulatory-review-period-for-purposes-of-patent-extension-incivek	11/23/2010	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/23/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=201917	2001	181			1		1					
202022	Edurant	rilpivirine	FI96A8X663	Antiviral	small molecule	NDA	10/29/2004		October 29, 2004. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 29, 2004.	https://www.federalregister.gov/documents/2014/05/01/2014-09911/determination-of-regulatory-review-period-for-purposes-of-patent-extension-edurant	7/23/2010	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/20/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202022	2394	301										
202258	Victrelis	boceprevir	89BT58KELH	Antiviral	small molecule	NDA	6/15/2005		June 15, 2005. The applicant claims June 18, 2005, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 15, 2005, which was the date the applicant was informed that they could proceed with their proposed clinical investigations.	https://www.federalregister.gov/documents/2014/06/27/2014-15021/determination-of-regulatory-review-period-for-purposes-of-patent-extension-victrelis	11/15/2010	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/13/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202258	2158	179	1		1		1					
201280	Tradjenta	linagliptin	3X29ZEJ4R2	Endocrinology	small molecule	NDA	9/21/2005		September 21, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 21, 2005.	https://www.federalregister.gov/documents/2014/05/13/2014-10945/determination-of-regulatory-review-period-for-purposes-of-patent-extension-tradjenta	7/2/2010	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/2/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=201280	2049	304										
202379	Zytiga	abiraterone	G819A456D0	Oncology	small molecule	NDA	1/19/2006		January 19, 2006. The applicant claims January 28, 2006, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 19, 2006, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2013/02/28/2013-04645/determination-of-regulatory-review-period-for-purposes-of-patent-extension-zytiga	12/20/2010	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/28/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=202379	1925	129	1				1					
22399	Horizant	gabapentin enacarbil	75OCL1SPBQ	Neurology	small molecule	NDA	1/12/2005		January 12, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 12, 2005.	https://www.federalregister.gov/documents/2014/07/11/2014-16237/determination-of-regulatory-review-period-for-purposes-of-patent-extension-horizant	1/9/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/6/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022399	2275	817							1			
22405	Caprelsa	vandetanib	YO460OQ37K	Oncology	small molecule	NDA	4/16/2000		April 16, 2000. The applicant claims April 20, 2000, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 16, 2000, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2014/06/11/2014-13566/determination-of-regulatory-review-period-for-purposes-of-patent-extension-vandetanib	7/7/2010	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	4/6/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022405	4007	273		1	1		1			1		
125377	Yervoy	ipilimumab	6T8C155666	Oncology	antibody	BLA	8/12/2000		August 12, 2000. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 12, 2000.	https://www.federalregister.gov/documents/2014/05/01/2014-09910/determination-of-regulatory-review-period-for-purposes-of-patent-extension-yervoy	6/25/2010	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/25/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125377	3877	273	1	1	1		1			1		
201277	Gadavist	gadobutrol	1BJ477IO2L	Oncology	small molecule	NDA	7/8/1999		July 8, 1999. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 8, 1999.	https://www.federalregister.gov/documents/2014/01/23/2014-01307/determination-of-regulatory-review-period-for-purposes-of-patent-extension-gadavist	5/14/2010	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/14/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=201277	4267	304								1		
125370	Benlysta	belimumab	73B0K5S26A	Rheumatology	antibody	BLA	10/23/2001		October 23, 2001. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 23, 2001.	https://www.federalregister.gov/documents/2014/05/15/2014-11176/determination-of-regulatory-review-period-for-purposes-of-patent-extension-benlysta	6/9/2010	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/9/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125370	3424	273	1		1		1					
22522	Daliresp	roflumilast	0P6C6ZOP5U	Respiratory	small molecule	NDA	7/26/1999		July 26, 1999. The applicant claims December 19, 1999, as the date the investigational	https://www.federalregister.gov/documents/2014/01/23/2014-01306/determination-of-regulatory-review-period-for-purposes-of-patent-extension-daliresp	7/17/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/28/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022522	4235	591	1						1			
200796	Edarbi	azilsartan	F9NUX55P23	Cardiology	small molecule	NDA	4/19/2005		IND Filed: 19 Apr 2005 (IND 71,867)	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/200796Orig1s000OtherR.pdf	4/27/2010	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/25/2011	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/200796sOrig1s000_Edarbi_TOC.cfm	2138	304								1		
125385	Corifact	factor XIII concentrate (human)	F7R0FBC1XD	Hematology	enzyme	BLA	8/1/1991		BI71.027D 3/101PK-(Otherwise known as Sdytu7D-101PK) 8/1991 to 6/1992 To determine the PK of ea Factor chen(Human) XIII conctrate Prospective, randomized, double-blind, crossover, pilot. Study 302CL was conducted between July 1994 and May 1996. A total of 173 unique subjects received at least one dose of Factor XIII Concentrate (Human) in the 11 supportive studies. Of these 173 subjects, 35 received Factor XIII Concentrate (Human) in ---b(4)---------- Studies 301CL and 302CL. The 2 subjects enrolled in Study 7MN-101PK, extension were also enrolled in Study 7MN-101PK.	https://wayback.archive-it.org/7993/20170722071412/https://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/ucm244147.htm	8/18/2010	https://wayback.archive-it.org/7993/20170723024727/https://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/UCM246670.pdf	2/17/2011	https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/corifact	7140	183		1	1		1	1				
22567	Viibyrd	vilazodone	S239O2OOV3	Neurology	small molecule	NDA	12/24/1997		December 24, 1997. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 24, 1997.	https://www.federalregister.gov/documents/2012/04/06/2012-8341/determination-of-regulatory-review-period-for-purposes-of-patent-extension-viibryd	3/22/2010	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/21/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022567	4776	305								1		
22408	Natroba	spinosad	XPA88EAP6V	Other Infectious disease	small molecule	NDA	11/11/2004		November 11, 2004. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 11, 2004.	https://www.federalregister.gov/documents/2012/04/06/2012-8337/determination-of-regulatory-review-period-for-purposes-of-patent-extension-natroba	1/22/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/18/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022408	2259	726							1			
22454	DaTscan	ioflupane I-123	3MM99T8R5Q	Neurology	small molecule	NDA	NA	Original IND submission date not provided	The applicant claims June 19, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that no IND was submitted under subsection 505(i) of the FFD&C Act for this human drug product.	https://www.federalregister.gov/documents/2012/04/06/2012-8340/determination-of-regulatory-review-period-for-purposes-of-patent-extension-datscan	3/9/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/14/2011	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022454	NA	676					1		1		1	
201532	Halaven	eribulin	LR24G6354G	Oncology	small molecule	NDA	4/30/2003		April 30, 2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 30, 2003.	https://www.federalregister.gov/documents/2012/05/03/2012-10716/determination-of-regulatory-review-period-for-purposes-of-patent-extension-halaven	3/30/2010	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/15/2010	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=201532	2756	230			1		1					
22505	Egrifta	tesamorelin	MQG94M5EEO	Other Infectious disease	protein	BLA	11/15/2001		November 15, 2001. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 15, 2001.	https://www.federalregister.gov/documents/2012/05/04/2012-10808/determination-of-regulatory-review-period-for-purposes-of-patent-extension-egrifta	5/29/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	11/10/2010	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022505	3282	530	1									
200327	Teflaro	ceftaroline fosamil	7P6FQA5D21	Antibacterial	small molecule	NDA	1/12/2005		January 12, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 12, 2005.	https://www.federalregister.gov/documents/2012/04/06/2012-8339/determination-of-regulatory-review-period-for-purposes-of-patent-extension-teflaro	12/30/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/29/2010	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=200327	2116	303			1							
200603	Latuda	lurasidone	22IC88528T	Neurology	small molecule	NDA	12/19/2000		December 19, 2000. The applicant claims December 17, 2000, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 19, 2000, when the project manager in the Division of Neuropharmacological Drug Products, Center for Drug Evaluation and Research, called the IND applicant on the behalf of the Division Director, to notify the IND applicant that studies under the IND may proceed. This date, December 19, 2000, rather than the claimed December 17, 2000, is also noted in Attachment F of the patent term extension application.	https://www.federalregister.gov/documents/2012/04/06/2012-8354/determination-of-regulatory-review-period-for-purposes-of-patent-extension-latuda	12/30/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/28/2010	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=200603	3600	302								1		
22512	Pradaxa	dabigatran	I0VM4M70GC	Cardiology	small molecule	NDA	8/6/2003		August 6, 2003. The applicant claims August 7, 2003, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 6, 2003, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2012/05/03/2012-10712/determination-of-regulatory-review-period-for-purposes-of-patent-extension-pradaxa	4/19/2010	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	10/19/2010	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022512	2631	183	1				1					
22527	Gilenya	fingolimod	3QN8BYN5QF	Immunology	small molecule	NDA	12/19/1998		December 19, 1998. The applicant claims December 25, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 19, 1998, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2012/05/04/2012-10819/determination-of-regulatory-review-period-for-purposes-of-patent-extension-gilenya	12/21/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/21/2010	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022527	4294	274	1		1		1					
125293	Krystexxa	pegloticase	R581OT55EA	Endocrinology	enzyme	BLA	12/19/2001		December 19, 2001. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 19, 2001.	https://www.federalregister.gov/documents/2012/05/03/2012-10697/determination-of-regulatory-review-period-for-purposes-of-patent-extension-krystexxa	10/31/2008	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	9/14/2010	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/125293s000TOC.cfm	3191	683		1			1		1	1		

App	Product	NME ingredients	unii	Therapeutic Class	Molecule Type	App Type	IND date	IND date note	indDateComment	IND date ref	App submitted date	App submitted date ref	App approval date	App ref	Days in clinical development	Days in review	First	Orphan	Fast track	Break-through	Priority	Acceler-ated	Non-first cycle	Black box	Diagnostic imaging	Animal rule
22474	Ella	ulipristal	6J5J15Q2X8	Gynecology	small molecule	NDA	12/1/1995		IND 049381 was opened by National Institute of Child Health and Human Development (NICHD) on December 1, 1995	https://www.fda.gov/media/83208/download	10/15/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	8/13/2010	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022474s000TOC.cfm	5369	302										
125360	Xeomin	incobotulinumtoxina	E211KPY694	Gynecology	protein	BLA	6/29/2006		IND 12,821 for the treatment of cervical dystonia was submitted on December 1, 2005 and was released from clinical hold on June 29, 2006. BB-IND 100,163 was submitted May 3, 2006 for the indication of blepharospasm and was also allowed to proceed on June 29, 2006.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/125360s000MedR.pdf	7/2/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/30/2010	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/125360s0000TOC.cfm	1492	393								1		
22134	Lastacaft	alcaftadine	7Z8O94ECSX	Immunology	small molecule	NDA	8/1/2004		August 1, 2004. The applicant claims July 31, 2004, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 1, 2004, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2012/05/03/2012-10694/determination-of-regulatory-review-period-for-purposes-of-patent-extension-lastacaft	9/29/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	7/28/2010	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022134s000TOC.cfm	2187	302										
201023	Jevtana	cabazitaxel	51F690397J	Oncology	small molecule	NDA	10/30/1998		October 30, 1998. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 30, 1998.	https://www.federalregister.gov/documents/2012/05/04/2012-10828/determination-of-regulatory-review-period-for-purposes-of-patent-extension-jevtana	3/31/2010	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/17/2010	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/201023s000TOC.cfm	4248	78			1		1			1		
125320	Prolia	denosumab	4EQZ6YO2HI	Endocrinology	antibody	BLA	6/21/2001		June 21, 2001. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 21, 2001.	https://www.federalregister.gov/documents/2012/05/07/2012-10959/determination-of-regulatory-review-period-for-purposes-of-patent-extension-prolia	12/19/2008	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	6/1/2010	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125320	3267	529	1						1			
22252	Natazia	dienogest	46M3EV8HHE	Gynecology	small molecule	NDA	11/17/2004		IND 64,809 was submitted to the FDA on Nov 17, 2004	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022252_Orig-1_MedR.pdf	7/6/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	5/6/2010	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022252	1996	304								1		
125197	Provenge	sipuleucel-T	8Q622VDR18	Oncology	virus	BLA	12/22/1996		22 DEC 1996 IND Original submission, BB-IND 6933, in effect. Phase 1 trial initiated.	https://web.archive.org/web/20110328162913/https://www.fda.gov/downloads/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/UCM214540.pdf	11/9/2006	https://wayback.archive-it.org/7993/20170723023808/https://www.fda.gov/downloads/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/UCM213114.pdf	4/29/2010	https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/provenge-sipuleucel-t	4876	1267	1		1		1		1			
21201	Asclera	polidocanol	0AWH8BFG9A	Hematology	small molecule	NDA	7/2/1990		The initial IND 35,138 was first submitted to Division of Medical of Imaging, Surgical and Dental Drug products on 02-Jul-1990	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/021201s000_Medr.pdf	10/1/1999	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/30/2010	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021201	7211	3833							1			
22562	Carbaglu	carglumic acid	5L0HB4V1EW	Endocrinology	small molecule	NDA	NA	Original IND submission date not provided	This research IND was opened by M. Tuchman to study the effect of carglumic acid on several urea cycle disorders including NAGS deficiency. original Orphan Europe IND: 61,265. According to information in the original IND submission dated July 8, 2003. A Pre-IND meeting was held with the Division of Metabolic and Endocrinology Products on July 8, 2002, and the IND (IND 61,265) was received on July 17, 2003. This submission covers the treatment of 24 patients throughout Europe over at least a 15 year period, with currently 19 surviving patients.	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022562s000crossr.pdf	6/18/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	3/18/2010	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022562	NA	273	1	1	1		1					
22575	Vpriv	velaglucerase alfa	23HYE36B0I	Endocrinology	enzyme	BLA	1/30/2004		January 30, 2004. The applicant claims May 20, 2004, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 30, 2004, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2011/03/21/2011-6514/determination-of-regulatory-review-period-for-purposes-of-patent-extension-vpriv	8/31/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/26/2010	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022575s000TOC.cfm	2219	179		1	1		1					
125338	Xiaflex	collagenase Clostridium Histolyticum	9X7O8V25IT	Orthopedics	enzyme	BLA	8/24/1995		August 24, 1995. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 24, 1995.	https://www.federalregister.gov/documents/2014/06/03/2014-12808/determination-of-regulatory-review-period-for-purposes-of-patent-extension-xiaflex	2/27/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	2/2/2010	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125338	5276	340	1	1			1					
22341	Victoza	liraglutide	839I73S42A	Endocrinology	peptide	NDA	11/5/2000		November 5, 2000. The applicant claims October 5, 2000, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 5, 2000, which was 30 days after FDA receipt of the IND.	https://www.federalregister.gov/documents/2012/05/02/2012-10517/determination-of-regulatory-review-period-for-purposes-of-patent-extension-victoza	5/23/2008	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/25/2010	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022341s000TOC.cfm	3368	612								1		
22250	Ampyra	dalfampridine	BH3B64OKL9	Neurology	small molecule	NDA	2/10/1983		February 10, 1983. The applicant claims January 1, 1980, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND was initially placed on clinical hold. The applicant was informed that the investigational studies were allowed to proceed on February 10, 1983, the effective date of the IND.	https://www.federalregister.gov/documents/2011/03/09/2011-5312/determination-of-regulatory-review-period-for-purposes-of-patent-extension-ampyra	4/22/2009	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/22/2010	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022250	9843	275		1			1					
125276	Actemra	tocilizumab	I031V2H011	Rheumatology	antibody	BLA	11/4/2004		November 4, 2004. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 4, 2004.	https://www.federalregister.gov/documents/2011/05/31/2011-13388/determination-of-regulatory-review-period-for-purposes-of-patent-extension-actemra	11/19/2007	https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals	1/8/2010	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/125276s000TOC.cfm	1891	781	1						1	1		