

Supporting Information: jm-2023-02239b

Chirality of New Drug Approvals (2013-2022): Trends and Perspectives

Rebecca U. McVicker^{1,2} and Niamh M. O’Boyle^{1*}

¹School of Pharmacy and Pharmaceutical Sciences, Trinity Biomedical Sciences Institute, Trinity College Dublin, 152 - 160 Pearse St, Dublin 2, D02 R590 Ireland

²Gamlen Tableting Ltd, 3 Stanton Way, London SE26 5FU, United Kingdom

Corresponding Author Information: Email: nioboyle@tcd.ie

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Methods

Terminology is used in accordance with IUPAC (International Union of Pure and Applied Chemistry) definitions stated in “Basic Terminology of Stereochemistry”.(1)

COMPILING EMA NEW DRUG APPROVALS DATA

The EMA “Human Medicines: highlights of (year)” reports were used to identify medicines which contained a NAS which were approved by the EMA in the years 2015 to 2022.(2) These reports provide the trade names of new medicines which have been approved each year and classify them according to their general therapeutic area. Those which contain a NAS are highlighted. No other information on the drug is provided. Based on these reports a list was compiled of the trade names of all medicines approved by the EMA in the period 2015-2022 which contained a NAS.

This list was then cross-referenced with a spreadsheet listing all medicine European Public Assessment Reports (EPARs) downloaded from the EMA website.(3) This spreadsheet provides significantly more detail than the highlights reports including medicine name, active substance(s), exact marketing authorisation date, use/indication etc. It does not, however, indicate which medicines contain active substances which have not previously been authorised thus necessitating the use of the “Human Medicines: highlights of (year)” reports.

The final stage in compiling the EMA data was classification of the NASs according to their chirality. The list of active substances was firstly filtered to remove the majority of biologics. This was achieved by removing drugs classed as vaccines then leveraging naming conventions used for biopharmaceuticals. NASs whose name contained the suffixes listed in

Table S1 were classified as biologics and not considered for further classification. Similarly, all vaccines were classed as biologics and not further classified.

The remaining medicines were then classified according to their chirality; chiral or achiral. Some additional biologics and non-biologic macromolecules were identified which were excluded from the chirality classification. Chiral molecules were further classified according to whether they are marketed as a single enantiomer or as a racemate. For simplicity, mixtures of diastereomers were classified as racemic drugs. Chiral drug molecules were also classified based on their type of chirality and, in the case of molecules containing one or more stereocentres, the number and stereocentre type. This was achieved by accessing the EPARs on the EMA website for each medicine. The Active Substance section of each report provides the structure of the active substance and details of the molecule’s chirality.

As the EMA “Human Medicines: highlights of (year)” reports were not published prior to 2015, an alternative approach was employed to the compilation of EMA data for years 2013 and 2014. The list of all medicines approved in those years from the Medicine EPAR spreadsheet was filtered to remove biologics. The EPARs for all remaining medicines were accessed on the EMA website. These reports were used to identify which active substances were NASs and also classify them according to their chirality as described above.

Table S1. Naming conventions for selected groups of biological drugs. (4)

Biological Drug Group	Suffix
Antisense oligonucleotides	-rsen
Cell therapies	-cel
Enzymes	-ase
Gene therapies	-gene
Gene therapy vectors	-vec
Monoclonal antibodies	-mab
Peptides and glycopeptides	-tide

COMPILING FDA NEW DRUG APPROVALS DATA

Data on FDA NME drug approvals was collected from the FDA web page “New Drugs at FDA: CDER’s New Molecular Entities and New Therapeutic Biological Products”.⁽⁵⁾ This site lists the trade names of all medicines approved by the FDA since 2015 that contain NMEs or NBEs. In addition, it provides the name of the new active substance, approval date and the medicine’s approved use. Biologics were filtered from the extracted list based on their nomenclature as described above (**Table S1**). The remaining medicines were cross-referenced with the EMA list such that the classifications of medicines also appearing in the EMA list could be transposed. In order to classify the remaining NMEs according to their chirality, their structures were obtained from PubChem, the website of the US National Library of Medicine.⁽⁶⁾ The stereochemistry of each compound was confirmed using the Global Substance Registration System website.⁽⁷⁾

As data has previously been published by Modroiu and Hancu classifying FDA drug approvals from 2010-2020 based on their chirality, only new FDA drug approvals from 2020-2022 were analysed as part of the study.⁽⁸⁾ 2020 was included in this analysis to confirm that the previously published data was replicated using the approach described here.

COMPILING CHIRAL SWITCH DATA

In order to identify new active substances that had been brought to market in the last ten years using the chiral switch approach, the naming conventions for chiral switch drugs was leveraged. The prefixes *es-* and *ar-* may be used where a racemate is chiral switched to the *S* or *R* enantiomer, respectively. Alternatively, the prefixes *dextro-* or *dex-* may be used for a chiral switch drug that displays dextrorotatory optical activity or *levo-* or *lev-* where is displays levorotatory optical activity.⁽⁹⁾ The EPARs spreadsheet from the EMA website was filtered for the relevant time period (2013-2022).⁽³⁾ Searches for the chiral switch prefixes were carried out within the filtered list. Each search result was examined to determine whether it was the result of chiral switch within the period of interest. Several active substances fulfilled the search criteria but were not the result of a chiral switch strategy e.g. artesunate, aripiprazole, estetrol monohydrate. Others were the result of chiral switching but had previously been marketed prior to 2013 e.g. esomeprazole, levofloxacin.

The same search procedure was applied to the compiled list of FDA drug approvals from 2020-2022. For the years 2013-2019, this search procedure was applied to the relevant lists of new drug approvals on the FDA web page “New Drugs at FDA: CDER’s New Molecular Entities and New Therapeutic Biological Products”.⁽⁵⁾

SEARCH STRATEGY LIMITATIONS

A limitation of this search strategy is that axial chirality arising from atropisomerism has the potential to be overlooked, specifically in the case of Class II atropisomers. Stable Class III atropisomers are expected to be clearly identified and Class I molecules are not considered chiral.

Table S2. Comparison of the number and percentage of biologic and small molecule NTEs approved by the FDA from 2020-2022.

Year	Biologic		Small Molecule		Total No.
	No.	%	No.	%	
2020	16	31	37	69	53
2021	20	39	30	61	50
2022	19	53	17	47	36
Total 2020-2022	55	40	84	60	139

Table S3. Comparison of the number and percentage of achiral, single enantiomer and racemic NMEs approved by the FDA between 2002-2022.

Data for years 2020-2022 was gathered by the author. Further data was compiled from reference (8) (years 2010-2020) and reference (10) (years 2002-2011).

Year	Achiral		Single Enantiomer		Racemate		Total No.
	No.	%	No.	%	No.	%	
2002	7	41	8	47	2	12	17
2003	6	32	10	53	3	16	19
2004	10	34	17	59	2	6.9	29
2005	4	25	11	69	1	6.3	16
2006	2	11	12	67	4	22	18
2007	4	25	11	69	1	6.3	16
2008	8	38	11	52	2	10	21
2009	6	30	7	35	7	35	20
2010	6	40	9	60	0	0.0	15
2011	9	38	12	50	3	13	24
2012	13	39	20	61	0	0.0	33
2013	10	40	14	56	1	4.0	25
2014	7	24	22	76	0	0.0	29
2015	12	36	18	55	3	9.0	33
2016	4	36	7	64	0	0.0	11
2017	11	41	16	59	0	0.0	27
2018	13	37	20	57	2	5.7	35
2019	16	47	18	53	0	0.0	34
2020	16	43	19	51	2	5.0	37
2021	8	27	21	70	1	3.3	30
2022	8	47	8	47	1	5.9	17
Total 2003-2012	68	32	120	57	23	11	211
Total 2013-2022	105	38	163	59	10	3.6	278
Total 2002-2022	180	36	291	58	35	6.9	506

Table S4. Comparison of the number and percentage of biologic and small molecule NAs approved by the EMA from 2013-2022.

Year	Biologic		Small Molecule		Other		Total No.
	No.	%	No.	%	No.	%	
2013	15	45	18	55	0	0.0	33
2014	11	31	24	67	1	2.8	36
2015	16	48	17	52	0	0.0	33
2016	12	41	16	55	1	3.4	29
2017	17	53	14	44	1	3.1	32
2018	26	62	16	38	0	0.0	42
2019	14	50	14	50	0	0.0	28
2020	20	53	18	47	0	0.0	38
2021	22	49	23	51	0	0.0	45
2022	35	66	18	34	0	0.0	53
Total 2013-2017	71	44	89	55	3	1.8	163
Total 2018-2022	117	57	89	43	0	0.0	206
Total 2013-2022	188	51	178	48	3	0.8	369

Table S5. Comparison of the number and percentage of achiral, single enantiomer and racemic small molecule NASs approved by the EMA from 2013-2022.

Year	Achiral		Single Enantiomer		Racemate		Total No.
	No.	%	No.	%	No.	%	
2013	11	61	6	33	1	5.6	18
2014	10	42	14	58	0	0.0	24
2015	6	35	9	53	2	12	17
2016	7	44	8	50	1	6.3	16
2017	6	43	8	57	0	0.0	14
2018	8	50	8	50	0	0.0	16
2019	4	29	10	71	0	0.0	14
2020	8	44	10	56	0	0.0	18
2021	15	65	8	35	0	0.0	23
2022	6	33	12	67	0	0.0	18
Total 2013-2017	40	45	45	51	4	4.5	89
Total 2018-2022	41	46	48	54	0	0.0	89
Total 2013-2022	81	46	93	52	4	2.2	178

Table S6. Categorisation of biologic, achiral and chiral NASs approved by the EMA between 2013-2022 according to the general therapeutic area for which they are indicated.

Therapeutic Area	Biologic	Achiral	Chiral	Other
	%	%	%	%
Cancer	47	33	20	0
Cardiovascular	40	40	20	0
Covid-19	85	0	15	0
Dermatology	64	27	0	9
Diagnostic agents	20	60	0	20
Endocrinology	67	4	30	0
Haematology/ Haemostaseology	68	16	16	0
Hepatology/ Gastroenterology	43	0	57	0
Immunology/ Rheumatology	61	11	28	0
Infections	18	5	77	0
Metabolism	50	25	25	0
Neurology	53	34	13	0
Ophthalmology	86	0	14	0
Other	0	0	100	0
Pneumology/ Allergology	22	26	52	0
Psychiatry	0	33	67	0
Reproductive	0	50	50	0
Uro-nephrology	38	38	13	13
Vaccines	100	0	0	0

Table S7. Comparison of the number of stereocentres present in chiral small molecule NMEs approved by the FDA between 2020-2022.

Year	No. of NMEs with X No. of Stereocentres											
	1	2	3	4	5	6	7	8	9	10	11	12
2020	10	1	1	2	0	4	1	1	0	1	0	0
2021	7	6	3	3	0	0	1	0	0	0	0	2
2022	5	1	1	0	0	1	0	1	0	0	0	0

Table S8. Comparison of the number of stereocentres present in chiral small molecule NASs approved by the EMA between 2013-2022.

Year	No. of NAS with X No. of Stereocentres											
	1	2	3	4	5	6	7	8	9	10	11	12
2013	4	0	1	1	1	0	0	0	0	0	0	0
2014	3	3	0	1	3	4	0	0	0	0	0	0
2015	3	2	4	1	1	0	0	0	0	0	0	0
2016	1	2	1	1	1	1	1	0	1	0	0	0
2017	1	2	1	1	0	0	1	2	0	0	0	0
2018	2	2	1	1	1	1	0	0	0	0	0	0
2019	3	4	0	2	1	0	0	0	0	0	0	0
2020	5	2	1	0	0	1	0	0	0	0	1	0
2021	4	2	0	0	0	0	1	1	0	0	0	0
2022	4	1	2	2	0	2	0	0	0	0	0	1

FDA NTE Classification (2020-2022)

Table S9. All medicines containing new therapeutic entities (NTEs) approved for marketing authorisation by the FDA from 2020-2022 classified as either biologic, achiral, single enantiomer or racemate.

Where more than one active substance is listed, the NTE(s) is shown in bold. Where a medicine contains more than one NTE, an additional entry has been added for each additional NTE. Data was gathered from the FDA website and excludes “vaccines, allergenic products, blood and blood products, plasma derivatives, cellular and gene therapy products, or other products that the Center for Biologics Evaluation and Research approved”.(5)

Note: an Excel file containing these tables is also available as Supporting Information.

Medicine Name	Specific Therapeutic Area	Active Substance	Marketing Authorisation Date	Drug Type/ Chirality	No. Stereo-centres	Type of Stereo-centres
NexoBrid	To remove eschar in adults with deep partial thickness or full thickness thermal burns	anacaulase-bcdb	28/12/2022	Biologic	-	-
Briumvi	To treat relapsing forms of multiple sclerosis	ublituximab-xiiy	28/12/2022	Biologic	-	-
Xenoview	To evaluate pulmonary function and imaging	hyperpolarized Xe-129	23/12/2022	Achiral	-	-
Lunsumio	To treat adults with relapsed or refractory follicular lymphoma, a type of non-Hodgkin lymphoma	mosunetuzumab-axgb	22/12/2022	Biologic	-	-
Sunlenca	To treat adults with HIV whose HIV infections cannot be successfully treated with other available treatments due to resistance, intolerance, or safety considerations Press Release	lenacapavir	22/12/2022	Single Enantiomer	3	C
Krazati	To treat KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer in adults who have received at least one prior systemic therapy	adagrasib	12/12/2022	Single Enantiomer	2	C
Rezlidhia	To treat adults with relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation	olutasidenib	01/12/2022	Single Enantiomer	1	C
Tziold	To delay the onset of stage 3 type 1 diabetes Press Release	teplizumab-mzww	18/11/2022	Biologic	-	-

Elahere	To treat patients with recurrent ovarian cancer that is resistant to platinum therapy	mirvetuximab soravtansine-gynx	14/11/2022	Biologic	-	-
Tecvayli	To treat relapsed or refractory multiple myeloma among adults who have received at least four specific lines of therapy	teclistamab-cqyv	25/10/2022	Biologic	-	-
Imjudo	To treat unresectable hepatocellular carcinoma	tremelimumab	21/10/2022	Biologic	-	-
Lytgobi	To treat intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements	futibatinib	30/09/2022	Single Enantiomer	1	C
Omlonti	To reduce elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	oomidenepag isopropyl ophthalmic solution	22/09/2022	Achiral	-	-
Elucirem	To detect and visualize lesions, together with MRI, with abnormal vascularity in the central nervous system and the body	gadopiclenol	21/09/2022	Racemate	6	C
Terlivaz	To improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function	terlipressin	14/09/2022	Biologic	-	-
Rolvedon	To decrease the incidence of infection in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia	eflapegrastim	09/09/2022	Biologic	-	-
Sotyktu	To treat moderate-to-severe plaque psoriasis	deucravacitinib	09/09/2022	Achiral	-	-
Daxxify	To treat moderate-to-severe glabellar lines associated with corrugator and/or procerus muscle activity	daxibotulinumtoxinA-lanm	07/09/2022	Biologic	-	-
Spevigo	To treat generalized pustular psoriasis flares	spesolimab-sbzo	01/09/2022	Biologic	-	-
Xenpozyme	To treat Acid Sphingomyelinase Deficiency Press Release	Olipudase alfa	31/08/2022	Biologic	-	-
Amvuttra	To treat polyneuropathy of hereditary transthyretin-mediated amyloidosis	vutrisiran	13/06/2022	Biologic	-	-
Vtama	To treat plaque psoriasis	tapinarof	23/05/2022	Achiral	-	-
Mounjaro	To improve blood sugar control in diabetes, in addition to diet and exercise Press Release	tirzepatide	13/05/2022	Biologic	-	-
Voquezna	To treat Helicobacter pylori infection	vonoprazan, amoxicillin, and clarithromycin	03/05/2022	Achiral	-	-

Camzyos	To treat certain classes of obstructive hypertrophic cardiomyopathy	mavacamten	28/04/2022	Single Enantiomer	1	C
Vivjoa	To reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are not of reproductive potential	oteseconazole	26/04/2022	Single Enantiomer	1	C
Pluvicto	To treat prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer following other therapies	lutetium (177Lu) vipivotide tetraxetan	23/03/2022	Biologic	-	-
Opdualag	To treat unresectable or metastatic melanoma	nivolumab and relatlimab-rmbw	18/03/2022	Biologic	-	-
Ztalmy	To treat seizures in cyclin-dependent kinase-like 5 deficiency disorder	ganaxolone	18/03/2022	Single Enantiomer	8	C
Vonjo	To treat intermediate or high-risk primary or secondary myelofibrosis in adults with low platelets	pacritinib	28/02/2022	Achiral	-	-
Pyrukynd	To treat hemolytic anemia in pyruvate kinase deficiency	mitapivat	17/02/2022	Achiral	-	-
Enjaymo	To decrease the need for red blood cell transfusion due to hemolysis in cold agglutinin disease	sutimlimab-jome	04/02/2022	Biologic	-	-
Vabysmo	To treat neovascular (wet) aged-related macular degeneration and diabetic macular edema	faricimab-svoa	28/01/2022	Biologic	-	-
Kimmtrak	To treat unresectable or metastatic uveal melanoma	tebentafusp-tebn	25/01/2022	Biologic	-	-
Cibinqo	To treat refractory, moderate-to-severe atopic dermatitis	abrocitinib	14/01/2022	Achiral	-	-
Quviviq	To treat insomnia	daridorexant	07/01/2022	Single Enantiomer	1	C
Adbry	To treat moderate-to-severe atopic dermatitis	tralokinumab-ldrm	27/12/..021	Biologic	-	-
Leqvio	To treat heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease as an add-on therapy	inclisiran	22/12/2021	Biologic	-	-
Vyvgart	To treat generalized myasthenia gravis	efgartigimod alfa-fcab	17/12/2021	Biologic	-	-
Tezpire	To treat severe asthma as an add-on maintenance therapy	tezepelumab-ekko	17/12/2021	Biologic	-	-
Cytalux	To help identify ovarian cancer lesions	pafolacianine	29/11/2021	Single Enantiomer	1	C
Livtency	To treat post-transplant cytomegalovirus (CMV) infection/disease that does not respond (with or without	maribavir	23/11/2021	Single Enantiomer	4	C

	genetic mutations that cause resistance) to available antiviral treatment for CMV					
Voxzogo	To improve growth in children five years of age and older with achondroplasia and open epiphyses	vosoritide	19/11/2021	Biologic	-	-
Besremi	To treat polycythemia vera, a blood disease that causes the overproduction of red blood cells	ropeginterferon alfa-2b-njft	12/11/2021	Biologic	-	-
Scemblix	To treat Philadelphia chromosome-positive chronic myeloid leukemia with disease that meets certain criteria	asciminib	29/10/2021	Single Enantiomer	1	C
Tavneos	To treat severe active anti-neutrophil cytoplasmic autoantibody-associated vasculitis (granulomatosis with polyangiitis and microscopic polyangiitis) in combination with standard therapy, including glucocorticoids	avacopan	07/10/2021	Single Enantiomer	2	C
Livmarli	To treat cholestatic pruritus associated with Alagille syndrome	maralixibat	29/09/2021	Single Enantiomer	2	C
Qulipta	To prevent episodic migraines	atogepant	28/09/2021	Single Enantiomer	4	C
Tivdak	To treat recurrent or metastatic cervical cancer with disease progression on or after chemotherapy	tisotumab vedotin-tftv	20/09/2021	Biologic	-	-
Exkivity	To treat locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor exon 20 insertion mutations	mobocertinib	15/09/2021	Achiral	-	-
Skytrofa	To treat short stature due to inadequate secretion of endogenous growth hormone	lonapegsomatropin-tcgd	25/08/2021	Biologic	-	-
Korsuva	To treat moderate-to-severe pruritus associated with chronic kidney disease in certain populations	difelikefalin	23/08/2021	Biologic	-	-
Welireg	To treat von Hippel-Lindau disease under certain conditions	belzutifan	13/08/2021	Single Enantiomer	3	C
Nexviazyme	To treat late-onset Pompe disease	avalglucosidase alfa-ngpt	06/08/2021	Biologic	-	-
Saphnelo	To treat moderate-to severe systemic lupus erythematosus along with standard therapy	anifrolumab-fnia	30/07/2021	Biologic	-	-
Bylvay	To treat pruritus	odevixibat	20/07/2021	Single Enantiomer	2	C
Rezurock	To treat chronic graft-versus-host disease after failure of at least two prior lines of systemic therapy	belumosudil	16/07/2021	Achiral	-	-

fexinidazole	To treat human African trypanosomiasis caused by the parasite <i>Trypanosoma brucei gambiense</i>	fexinidazole	16/07/2021	Achiral	-	-
Kerendia	To reduce the risk of kidney and heart complications in chronic kidney disease associated with type 2 diabetes	finerenone	09/07/2021	Single Enantiomer	1	C
Rylaze	To treat acute lymphoblastic leukemia and lymphoblastic lymphoma in patients who are allergic to E. coli-derived asparaginase products, as a component of a chemotherapy regimen	asparaginase erwinia chrysanthemi (recombinant)-rywn	30/06/2021	Biologic	-	-
Aduhelm	To treat Alzheimer's disease	aducanumab-avwa	07/06/2021	Biologic	-	-
Brexafemme	To treat vulvovaginal candidiasis	ibrexafungerp	01/06/2021	Single Enantiomer	12	C
Lybalvi	To treat schizophrenia and certain aspects of bipolar I disorder	olanzapine and samidorphan	28/05/2021	Single Enantiomer	3	C
Truseltiq	To treat cholangiocarcinoma whose disease meets certain criteria	infigratinib	28/05/2021	Achiral	-	-
Lumakras	To treat types of non-small cell lung cancer	sotorasib	28/05/2021	Single Enantiomer	1	C
Pylarify	To identify prostate-specific membrane antigen-positive lesions in prostate cancer	piflufolostat F 18	26/05/2021	Single Enantiomer	2	C
Rybrevant	To treat a subset of non-small cell lung cancer	amivantamab-vmjw	21/05/2021	Biologic	-	-
Empaveli	To treat paroxysmal nocturnal hemoglobinuria	pegcetacoplan	5/14/2021	Biologic	-	-
Zynlonta	To treat certain types of relapsed or refractory large B-cell lymphoma	loncastuximab tesirine-lpyl	23/04/2021	Biologic	-	-
Jemperli	To treat endometrial cancer	dostarlimab-gxly	23/04/2021	Biologic	-	-
Nextstellis	To prevent pregnancy	drospirenone and estetrol	15/04/2021	Single Enantiomer	7	C
Qelbree	To treat attention deficit hyperactivity disorder	viloxazine	02/04/2021	Racemate	1	C
Zegalogue	To treat severe hypoglycemia	dasiglucagon	22/03/2021	Biologic	-	-
Ponvory	To treat relapsing forms of multiple sclerosis	ponesimod	18/03/2021	Single Enantiomer	1	C
Fotivda	To treat renal cell carcinoma	tivozanib	10/03/2021	Achiral	-	-
Azstarys	To treat attention deficit hyperactivity disorder	serdexmethylphenidate and dexamethylphenidate	02/03/2021	Single Enantiomer	3	C

Pepaxto	To treat relapsed or refractory multiple myeloma	melphalan flufenamide	26/02/2021	Single Enantiomer	2	C
Nulibry	To reduce the risk of mortality in molybdenum cofactor deficiency Type A	fosdenopterin	26/02/2021	Single Enantiomer	4	C
Amondys 45	To treat Duchenne muscular dystrophy	casimersen	25/02/2021	Biologic	-	-
Cosela	To mitigate chemotherapy-induced myelosuppression in small cell lung cancer	trilaciclib	12/02/2021	Achiral	-	-
Evkeeza	To treat homozygous familial hypercholesterolemia	evinacumab-dgnb	11/02/2021	Biologic	-	-
Ukoniq	To treat marginal zone lymphoma and follicular lymphoma	umbralisib	05/02/2021	Single Enantiomer	1	C
Tepmetko	To treat non-small cell lung cancer	tepotinib	03/02/2021	Achiral	-	-
Lupkynis	To treat lupus nephritis	voclosporin	22/01/2021	Single Enantiomer	12	C
Cabenuva	To treat HIV	cabotegravir and rilpivirine (co-packaged)	21/01/2021	Single Enantiomer	2	C
Verquvo	To mitigate the risk of cardiovascular death and hospitalization for chronic heart failure	vericiguat	19/01/2021	Achiral	-	-
Gemtesa	To treat overactive bladder	vibegron	23/12/2020	Single Enantiomer	4	C
Ebanga	To treat ebola	ansuvimab-zykl	21/12/2020	Biologic	-	-
Orgovyx	To treat advanced prostate cancer	relugolix	18/12/2020	Achiral	-	-
Margenza	To treat HER2+ breast cancer	margetuximab (anti-HER2 mAb)	16/12/2020	Biologic	-	-
Klisyri	To treat actinic Keratosis of the face or scalp	tirbanibulin	14/12/2020	Achiral	-	-
Cerianna	To treat patients with hereditary angioedema	berotralstat	03/12/2020	Single Enantiomer	1	C
Gallium 68 PSMA-11	For detection and localization of prostate cancer	Gallium 68 PSMA-11	01/12/2020	Single Enantiomer	2	C
Danyelza	To treat high-risk refractory or relapsed neuroblastoma	naxitamab-gqgk	25/11/2020	Biologic	-	-
Imcivree	To treat obesity and the control of hunger associated with pro-opiomelanocortin deficiency, a rare disorder that causes severe obesity that begins at an early age	setmelanotide	25/11/2020	Biologic	-	-
Oxlumo	To treat hyperoxaluria type 1	lumasiran	23/11/2020	Biologic	-	-

Zokinvy	To treat rare conditions related to premature aging	lonafarnib	20/11/2020	Single Enantiomer	1	C
Veklury	To treat COVID-19	remdesivir	22/10/2020	Single Enantiomer	6	C
Inmazoleb	To treat ebola virus	atoltivimab, maftivimab, and odesivimab-ebgn	14/10/2020	Biologic	-	-
Gavreto	To treat non-small lung cancer	pralsetinib	04/09/2020	Single Enantiomer	1	C
Detectnet	To help detect certain types of neuroendocrine tumors	copper Cu 64 dotatate injection	03/09/2020	Single Enantiomer	10	C
Sogroya	Growth hormone	somapacitan-beco	28/08/2020	Biologic	-	-
Winlevi	To treat acne	clascoterone	26/08/2020	Single Enantiomer	6	C
Enspryng	To treat neuromyelitis optica spectrum disorder	satralizumab-mwge	14/08/2020	Biologic	-	-
Viltepso	To treat Duchenne muscular dystrophy	viltolarsen	12/08/2020	Biologic	-	-
Olinvyk	To manage acute pain in certain adults	oliceridine	07/08/2020	Single Enantiomer	1	C
Evrysdi	To treat spinal muscular atrophy	risdiplam	07/08/2020	Achiral	-	-
Lampit	To treat Chagas disease in certain pediatric patients younger than age 18	nifurtimox	06/08/2020	Racemate	1	C
Blenrep	To treat multiple myeloma	belantamab mafodotin-blmf	05/08/2020	Biologic	-	-
Monjuvi	To treat relapsed or refractory diffuse large B-cell lymphoma	tafasitamab-cxix	31/07/2020	Biologic	-	-
Xeglyze	To treat head lice	abametapir	24/07/2020	Achiral	-	-
Inqovi	To treat adult patients with myelodysplastic syndromes	decitabine and cedazuridine	07/07/2020	Single Enantiomer	4	C
Rukobia	To treat HIV	fostemsavir	02/07/2020	Achiral	-	-
Byfavo	For sedation	remimazolam	02/07/2020	Single Enantiomer	1	C
Dojolvi	To treat molecularly long-chain fatty acid oxidation disorders	triheptanoin	30/06/2020	Achiral	-	-
Zepzelca	To treat metastatic small cell lung cancer	lurbinectedin	15/06/2020	Single Enantiomer	7	C
Uplizna	To treat neuromyelitis optica spectrum disorder	inebilizumab-cdon	11/06/2020	Biologic	-	-
Tauvid	Diagnostic agent for patients with Alzheimer's disease	flortaucipir F18	28/05/2020	Achiral	-	-

Artesunate	To treat severe malaria	artesunate	26/05/2020	Single Enantiomer	8	C
Cerianna	Diagnostic imaging agent for certain patients with breast cancer	fluoroestradiol F18	20/05/2020	Single Enantiomer	6	C
Qinlock	To treat advanced gastrointestinal-stromal tumors	ripretinib	15/05/2020	Achiral	-	-
Retevmo	To treat lung and thyroid cancers	selpercatinib	08/05/2020	Achiral	-	-
Tabrecta	To treat patients with non small cell lung cancer	capmatinib	06/05/2020	Achiral	-	-
Ongentys	To treat patients with Parkinson's disease experiencing "off" episodes	opicapone	24/04/2020	Achiral	-	-
Trodelyv	To treat adult patients with metastatic triple-negative breast cancer who received at least two prior therapies for metastatic disease	sacituzumab govitecan-hziy	22/04/2020	Biologic	-	-
Pemazyre	To treat certain patients with cholangiocarcinoma, a rare form of cancer that forms in bile ducts	pemigatinib	17/04/2020	Achiral	-	-
Tukysa	To treat advanced unresectable or metastatic HER2-positive breast cancer	tucatinib	17/04/2020	Achiral	-	-
Koselugo	To treat neurofibromatosis type 1, a genetic disorder of the nervous system causing tumors to grow on nerves	selumetinib	10/04/2020	Achiral	-	-
Zeposia	To treat relapsing forms of multiple sclerosis	ozanimod	25/03/2020	Single Enantiomer	1	C
Isturisa	To treat adults with Cushing's disease who either cannot undergo pituitary gland surgery or have undergone the surgery but still have the disease	osilodrostat	06/03/2020	Single Enantiomer	1	C
Sarclisa	To treat multiple myeloma	isatuximab	02/03/2020	Biologic	-	-
Nurtec ODT	To treat migraine	rimegepant	27/02/2020	Single Enantiomer	3	C
Barhemsys	To help prevent nausea and vomiting after surgery	amisulpride	26/02/2020	Racemate	1	C
Vyepti	For the preventive treatment of migraine in adults	eptinezumab-jjmr	21/02/2020	Biologic	-	-
Nexletol	To treat adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C	bempedoic acid	21/02/2020	Achiral	-	-

Pizensy	To treat chronic idiopathic constipation (CIC) in adults	lactitol	12/02/2020	Single Enantiomer	6	C
Tazverik	To treat epithelioid sarcoma	tazemetostat	23/01/2020	Achiral	-	-
Tepezza	To treat Thyroid eye disease	teprotumumab-trbw	21/01/2020	Biologic	-	-
Ayvakit	To treat adults with unresectable or metastatic gastrointestinal stromal tumor (GIST)	avapritinib	09/01/2020	Single Enantiomer	1	C

EMA NAS Classification (2013-2022)

Table S10. All medicines containing new active substances (NASs) approved for marketing authorisation by the EMA from 2013-2022 classified as either biologic, achiral, single enantiomer, racemate, polymer or herbal substance.

Where more than one active substance is listed, the NAS(s) is shown in bold. Where a medicine contains more than one NAS, an additional entry has been added for each additional NAS.

Note: an Excel file containing these tables is also available as Supporting Information.

Medicine Name	Specific Therapeutic Area	Active Substance	Marketing Authorisation Date	Drug Type/ Chirality	No. Stereo-centres	Type of Stereo-centres
Krystexxa	Gout	pegloticase	8/01/2013	Biologic	-	-
Bexsero	Meningitis, Meningococcal	outer membrane vesicles from neisseria meningitidis group b (strain nz 98/254), recombinant neisseria meningitidis group b fhbp fusion protein, recombinant neisseria meningitidis group b nada protein, recombinant neisseria meningitidis group b nhba fusion protein	13/01/2013	Biologic	-	-
Amyvid	Radionuclide Imaging	florbetapir (18f)	14/01/2013	Achiral	-	-
Tresiba	Diabetes Mellitus	insulin degludec	20/01/2013	Biologic	-	-
BindRen	Hyperphosphatemia	colestilan	21/01/2013	Achiral	-	-
Ryzodeg	Diabetes Mellitus	insulin aspart , insulin degludec	21/01/2013	Biologic	-	-
Lyxumia	Diabetes Mellitus, Type 2	lixisenatide	31/01/2013	Biologic	-	-
Zaltrap	Colorectal Neoplasms	aflibercept	1/02/2013	Biologic	-	-
Selincro	Alcohol-Related Disorders	nalmefene hydrochloride dihydrate	24/02/2013	Single Enantiomer	4	C

Perjeta	Breast Neoplasms	pertuzumab	4/03/2013	Biologic	-	-
Jetrea	Retinal Diseases	ocriplasmin	13/03/2013	Biologic	-	-
Bosulif	Leukemia, Myeloid	bosutinib (as monohydrate)	27/03/2013	Achiral	-	-
Stribild	HIV Infections	elvitegravir, cobicistat , emtricitabine, tenofovir disoproxil fumarate	24/05/2013	X	-	-
Iclusig	Leukemia, Myeloid; Leukemia, Lymphoid	ponatinib	1/07/2013	Achiral	-	-
Lonquex	Neutropenia	lipegfilgrastim	25/07/2013	Biologic	-	-
Lojuxta	Hypercholesterolemia	lomitapide	31/07/2013	Achiral	-	-
Imvanex	Smallpox Vaccine; Monkeypox virus	modified vaccinia ankara - bavarian nordic (mva-bn) virus	31/07/2013	Biologic	-	-
Imnovid	Multiple Myeloma	pomalidomide	5/08/2013	Racemate	1	C
Tafinlar	Melanoma	dabrafenib mesilate	26/08/2013	Achiral	-	-
Stivarga	Colorectal Neoplasms	regorafenib	26/08/2013	Achiral	-	-
Aubagio	Multiple Sclerosis	teriflunomide	26/08/2013	Achiral	-	-
Provenge	Prostatic Neoplasms	autologous peripheral-blood mononuclear cells including a minimum of 50 million autologous cd54+ cells activated with prostatic acid phosphatase granulocyte-macrophage colony-stimulating factor	6/09/2013	Biologic	-	-
Vipidia	Diabetes Mellitus, Type 2	alogliptin	18/09/2013	Single Enantiomer	1	C
Vipdomet	Diabetes Mellitus, Type 2	alogliptin benzoate , metformin hydrochloride	18/09/2013	Single Enantiomer	1	C
Incredync	Diabetes Mellitus, Type 2	alogliptin, pioglitazone	19/09/2013	Single Enantiomer	1	C
Tybost	HIV Infections	cobicistat	19/09/2013	Single Enantiomer	3	C
Giotrif	Carcinoma, Non-Small-Cell Lung	afatinib	25/09/2013	Single Enantiomer	1	C

Defitelio	Hepatic Venous Occlusive Disease	defibrotide	18/10/2013	Biologic	-	-
Vitekta	HIV Infections	elvitegravir	13/11/2013	Single Enantiomer	1	C
Xofigo	Prostatic Neoplasms	radium (223ra) dichloride	13/11/2013	Achiral	-	-
NovoEight	Hemophilia A	turoctocog alfa	13/11/2013	Biologic	-	-
Invokana	Diabetes Mellitus, Type 2	canagliflozin	15/11/2013	Single Enantiomer	5	C
Kadcyla	Breast Neoplasms	trastuzumab emtansine	15/11/2013	Biologic	-	-
Fluenz Tetra	Influenza, Human	a/victoria/2570/2019 (h1n1)pdm09 - like strain (a/victoria/1/2020, medi 340505) a/darwin/9/2021 (h3n2) - like strain (a/norway/16606/2021, medi 355293) b/austria/1359417/2021 - like strain (b/austria/1359417/2021, medi 355292) b/phuket/3073/2013 - like strain (b/phuket/3073/2013, medi 306444)	4/12/2013	Biologic	-	-
Brintellix	Depressive Disorder, Major	vortioxetine	18/12/2013	Achiral	-	-
Opsumit	Hypertension, Pulmonary	macitentan	20/12/2013	Achiral	-	-
Tivicay	HIV Infections	dolutegravir	16/01/2014	Single Enantiomer	2	C
Sovaldi	Hepatitis C, Chronic	sofosbuvir	16/01/2014	Single Enantiomer	6	5C, 1P
Tecfidera	Multiple Sclerosis	dimethyl fumarate	30/01/2014	Achiral	-	-
Neuraceq	Radionuclide Imaging; Alzheimer Disease	florbetaben (18f)	20/02/2014	Achiral	-	-
Sirturo	Tuberculosis, Multidrug-Resistant	bedaquiline fumarate	5/03/2014	Single Enantiomer	2	C
Eperzan	Diabetes Mellitus, Type 2	albiglutide	20/03/2014	Biologic	-	-
Cometriq	Thyroid Neoplasms	cabozantinib	21/03/2014	Achiral	-	-
Latuda	Schizophrenia	lurasidone	21/03/2014	Single Enantiomer	6	C

Adempas	Hypertension, Pulmonary	riociguat	27/03/2014	Achiral	-	-
Vokanamet	Diabetes Mellitus, Type 2	canagliflozin , metformin hydrochloride	23/04/2014	Single Enantiomer	5	C
Vimizim	Mucopolysaccharidosis IV	recombinant human n-acetylgalactosamine-6-sulfatase	27/04/2014	Biologic	-	-
Incruse Ellipta	Pulmonary Disease, Chronic Obstructive	umeclidinium bromide	28/04/2014	Achiral	-	-
Anoro Ellipta	Pulmonary Disease, Chronic Obstructive	umeclidinium bromide , vilanterol trifenate	8/05/2014	Achiral	-	-
Anoro Ellipta	Pulmonary Disease, Chronic Obstructive	umeclidinium bromide, vilanterol trifenate	8/05/2014	Single Enantiomer	1	C
Laventair Ellipta	Pulmonary Disease, Chronic Obstructive	umeclidinium bromide, vilanterol	8/05/2014		-	-
Olysio	Hepatitis C, Chronic	simeprevir	14/05/2014	Single Enantiomer	5	C
Entyvio	Colitis, Ulcerative; Crohn Disease	vedolizumab	22/05/2014	Biologic	-	-
Sylvant	Giant Lymph Node Hyperplasia	siltuximab	22/05/2014	Biologic	-	-
Jardiance	Diabetes Mellitus, Type 2	empagliflozin	22/05/2014	Single Enantiomer	6	C
Mekinist	Melanoma	trametinib	30/06/2014	Achiral	-	-
Plegridy	Multiple Sclerosis	peginterferon beta-1a	18/07/2014	Biologic	-	-
Nuwiq	Hemophilia A	simoctocog alfa	22/07/2014	Biologic	-	-
Gazyvaro	Leukemia, Lymphocytic, Chronic, B-Cell	obinutuzumab	22/07/2014	Biologic	-	-
Translarna	Muscular Dystrophy, Duchenne	ataluren	31/07/2014	Achiral	-	-
Vizamyl	Radionuclide Imaging; Alzheimer Disease	flutemetamol (18f)	22/08/2014	Achiral	-	-
Daklinza	Hepatitis C, Chronic	daclatasvir dihydrochloride	22/08/2014	Single Enantiomer	4	C

Velphoro	Hyperphosphatemia; Renal Dialysis	sucroferric oxyhydroxide	26/08/2014	Biologic	-	-
Triumeq	HIV Infections	dolutegravir sodium , lamivudine, abacavir (as sulfate)	31/08/2014	Single Enantiomer	2	C
Zydelig	Lymphoma, Non-Hodgkin; Leukemia, Lymphocytic, Chronic, B-Cell	idelalisib	18/09/2014	Single Enantiomer	1	C
Imbruvica	Lymphoma, Mantle-Cell; Leukemia, Lymphocytic, Chronic, B-Cell	ibrutinib	21/10/2014	Single Enantiomer	1	C
Harvoni	Hepatitis C, Chronic	ledipasvir , sofosbuvir	17/11/2014	Single Enantiomer	6	C
Lymphoseek	Radionuclide Imaging	tilmanocept	19/11/2014	Polymer	-	-
Trulicity	Diabetes Mellitus, Type 2	dulaglutide	21/11/2014	Biologic	-	-
Vargatef	Carcinoma, Non-Small-Cell Lung	nintedanib	21/11/2014	Achiral	-	-
Moventig	Constipation; Opioid-Related Disorders	naloxegol oxalate	7/12/2014	Single Enantiomer	5	C
Lynparza	Ovarian Neoplasms	olaparib	16/12/2014	Achiral	-	-
Cyramza	Stomach Neoplasms	ramucirumab	19/12/2014	Biologic	-	-
Scenesse	Protoporphyrin, Erythropoietic	afamelanotide	22/12/2014	Biologic	-	-
Tenkasi	Soft Tissue Infections; Skin Diseases, Bacterial	oritavancin diphosphate	18/03/2015	Biologic	-	-
Kengrexal	Acute Coronary Syndrome; Vascular Surgical Procedures	cangrelor	23/03/2015	Single Enantiomer	4	C
Sivextro	Soft Tissue Infections; Skin Diseases, Bacterial	tedizolid phosphate	23/03/2015	Single Enantiomer	1	C
Zykadia	Carcinoma, Non-Small-Cell Lung	ceritinib	6/05/2015	Achiral	-	-
Lenvima	Thyroid Neoplasms	lenvatinib mesilate	28/05/2015	Achiral	-	-

Gardasil 9	Condylomata Acuminata; Papillomavirus Infections; Immunization; Uterine Cervical Dysplasia	human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed)	10/06/2015	Biologic	-	-
Opdivo	Melanoma; Hodgkin Disease; Carcinoma, Renal Cell; Carcinoma, Non-Small-Cell Lung; Carcinoma, Transitional Cell; Squamous Cell Carcinoma of Head and Neck; Urologic Neoplasms; Mesothelioma; Colorectal Neoplasms	nivolumab	19/06/2015	Biologic	-	-
Lixiana	Stroke; Venous Thromboembolism	edoxaban tosilate	19/06/2015	Single Enantiomer	3	C
Hetlioz	Sleep Disorders, Circadian Rhythm	tasimelteon	3/07/2015	Single Enantiomer	2	C
Keytruda	Melanoma; Hodgkin Disease; Carcinoma, Renal Cell; Carcinoma, Non-Small-Cell Lung; Carcinoma, Transitional Cell; Squamous Cell Carcinoma of Head and Neck; Urologic Neoplasms; Endometrial Neoplasms	pembrolizumab	17/07/2015	Biologic	-	-
Repatha	Dyslipidemias; Hypercholesterolemia	evolocumab	17/07/2015	Biologic	-	-
Nivolumab BMS	Carcinoma, Non-Small-Cell Lung	nivolumab	20/07/2015	Biologic	-	-
Odomzo	Carcinoma, Basal Cell	sonidegib diphosphate	14/08/2015	Achiral	-	-
Unituxin	Neuroblastoma	dinutuximab	14/08/2015	Biologic	-	-

Farydak	Multiple Myeloma	panobinostat lactate anhydrous	28/08/2015	Racemate	1/1	C/C
Kanuma	Lipid Metabolism, Inborn Errors	sebelipase alfa	28/08/2015	Biologic	-	-
Strengiq	Hypophosphatasia	asfotase alfa	28/08/2015	Biologic	-	-
Zerbaxa	Bacterial Infections	ceftolozane sulfate , tazobactam sodium	18/09/2015	Single Enantiomer	2	C
Praluent	Dyslipidemias	alirocumab	23/09/2015	Biologic	-	-
Fexeric	Hyperphosphatemia; Renal Dialysis	ferric citrate coordination complex	23/09/2015	Achiral	-	-
Cresemba	Aspergillosis	isavuconazole	15/10/2015	Epimers	3	C
Obizur	Hemophilia A	susoctocog alfa	11/11/2015	Biologic	-	-
Elocta	Hemophilia A	efmoroctocog alfa	18/11/2015	Biologic	-	-
Orkambi	Cystic Fibrosis	lumacaftor , ivacaftor	18/11/2015	Achiral	-	-
Kyprolis	Multiple Myeloma	carfilzomib	19/11/2015	Single Enantiomer	5	C
Entresto	Heart Failure	sacubitril, valsartan	19/11/2015	Single Enantiomer	3	C
Genvoya	HIV Infections	elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide	19/11/2015	Single Enantiomer	3	1P, 2C
Cotellic	Melanoma	cobimetinib hemifumarate	20/11/2015	Single Enantiomer	1	C
Praxbind	Hemorrhage	idarucizumab	20/11/2015	Biologic	-	-
Blincyto	Precursor Cell Lymphoblastic Leukemia-Lymphoma	blinatumomab	23/11/2015	Biologic	-	-
Ravicti	Urea Cycle Disorders, Inborn	glycerol phenylbutyrate	26/11/2015	Achiral	-	-
Nucala	Asthma	mepolizumab	1/12/2015	Biologic	-	-
Imlygic	Melanoma	talimogene laherparepvec	16/12/2015	Biologic	-	-
Briviact	Epilepsy	brivaracetam	13/01/2016	Single Enantiomer	2	C

Episalvan	Wounds and Injuries; Wound Healing	betulae cortex	14/01/2016	Herbal Substance	-	-
Tagrisso	Carcinoma, Non-Small-Cell Lung	osimertinib mesilate	1/02/2016	Achiral	-	-
Portrazza	Carcinoma, Non-Small-Cell Lung	necitumumab	15/02/2016	Biologic	-	-
Zurampic	Hyperuricemia	lesinurad	18/02/2016	Racemate	0	n/a
Wakix	Narcolepsy	pitolisant	31/03/2016	Achiral	-	-
Lonsurf	Colorectal Neoplasms	trifluridine, tipiracil hydrochloride	25/04/2016	Achiral	-	-
Taltz	Psoriasis	ixekizumab	25/04/2016	Biologic	-	-
Empliciti	Multiple Myeloma	elotuzumab	11/05/2016	Biologic	-	-
Idelvion	Hemophilia B	albutrepenonacog alfa	11/05/2016	Biologic	-	-
Upravi	Hypertension, Pulmonary	selexipag	12/05/2016	Achiral	-	-
Alprolix	Hemophilia B	eftrenonacog alfa	12/05/2016	Biologic	-	-
Darzalex	Multiple Myeloma	daratumumab	20/05/2016	Biologic	-	-
Pandemic influenza vaccine (H5N1) MedImmune	Influenza, Human	reassortant influenza virus (live attenuated) of the following strain: a/vietnam/1203/2004 (h5n1) strain	20/05/2016	Biologic	-	-
Galafold	Fabry Disease	migalastat hydrochloride	25/05/2016	Single Enantiomer	4	C
Strimvelis	Severe Combined Immunodeficiency	autologous cd34+ enriched cell fraction that contains cd34+ cells transduced with retroviral vector that encodes for the human adenosine deaminase (ada) cDNA sequence from human haematopoietic stem/progenitor (cd34+) cells	26/05/2016	Biologic	-	-
Zavicefta	Pneumonia, Bacterial; Soft Tissue Infections; Pneumonia; Urinary Tract	avibactam sodium , ceftazidime pentahydrate	23/06/2016	Single Enantiomer	3	1N, 2C

	Infections; Gram-Negative Bacterial Infections					
Ongentys	Parkinson Disease	opicapone	24/06/2016	Achiral	-	-
Epclusa	Hepatitis C, Chronic	sofosbuvir, velpatasvir	6/07/2016	Single Enantiomer	6	C
Zepatier	Hepatitis C, Chronic	elbasvir , grazoprevir	22/07/2016	Single Enantiomer	5	C
Zepatier	Hepatitis C, Chronic	elbasvir, grazoprevir	22/07/2016	Single Enantiomer	7	C
Cinqaero	Asthma	reslizumab	15/08/2016	Biologic	-	-
Zalmoxis	Hematopoietic Stem Cell Transplantation; Graft vs Host Disease	allogeneic t cells genetically modified with a retroviral vector encoding for a truncated form of the human low affinity nerve growth factor receptor (δ l α ngfr) and the herpes simplex i virus thymidine kinase (hsv-tk mut2)	18/08/2016	Biologic	-	-
Truberzi	Irritable Bowel Syndrome; Diarrhea	eluxadoline	19/09/2016	Single Enantiomer	2	C
Ibrance	Breast Neoplasms	palbociclib	9/11/2016	Achiral	-	-
Lartruvo	Sarcoma	olaratumab	9/11/2016	Biologic	-	-
Parsabiv	Hyperparathyroidism, Secondary	etelcalcetide hydrochloride	11/11/2016	Biologic	-	-
Ninlaro	Multiple Myeloma	ixazomib citrate	21/11/2016	Single Enantiomer	1	C
Venclyxt	Leukemia, Lymphocytic, Chronic, B-Cell	venetoclax	4/12/2016	Achiral	-	-
Ocaliva	Liver Cirrhosis, Biliary	obeticholic acid	12/12/2016	Single Enantiomer	9	C
Afstyla	Hemophilia A	lonoctocog alfa	4/01/2017	Biologic	-	-
Zinplava	Enterocolitis, Pseudomembranous	bezlotoxumab	18/01/2017	Biologic	-	-
Olumiant	Arthritis, Rheumatoid	baricitinib	13/02/2017	Achiral	-	-

Alecensa	Carcinoma, Non-Small-Cell Lung	alectinib hydrochloride	16/02/2017	Achiral	-	-
Xeljanz	Arthritis, Rheumatoid	tofacitinib	22/03/2017	Single Enantiomer	2	C
Varuby	Vomiting; Nausea; Cancer	rolapitant	19/04/2017	Single Enantiomer	3	C
Axumin	Prostatic Neoplasms; Radionuclide Imaging	fluciclovine (18f)	21/05/2017	Achiral	-	-
Trumenba	Meningitis, Meningococcal	neisseria meningitidis serogroup b fhbp (recombinant lipidated fhbp (factor h binding protein)) subfamily a; neisseria meningitidis serogroup b fhbp (recombinant lipidated fhbp (factor h binding protein)) subfamily b	24/05/2017	Biologic	-	-
Brineura	Neuronal Ceroid-Lipofuscinoses	cerliponase alfa	30/05/2017	Biologic	-	-
Spinraza	Muscular Atrophy, Spinal	nusinersen sodium	30/05/2017	Biologic	-	-
Refixia	Hemophilia B	nonacog beta pegol	2/06/2017	Biologic	-	-
Kevzara	Arthritis, Rheumatoid	sarilumab	23/06/2017	Biologic	-	-
Besponsa	Precursor Cell Lymphoblastic Leukemia-Lymphoma	inotuzumab ozogamicin	28/06/2017	Biologic	-	-
Oxervate	Keratitis	recombinant human nerve growth factor	6/07/2017	Biologic	-	-
Spherox	Cartilage Diseases	spheroids of human autologous matrix-associated chondrocytes	10/07/2017	Biologic	-	-
Reagila	Schizophrenia	cariprazine hydrochloride	13/07/2017	Achiral	-	-
Kyntheum	Psoriasis	brodalumab	17/07/2017	Biologic	-	-
Veltassa	Hyperkalemia	patiromer sorbitex calcium	19/07/2017	Polymer	-	-
Maviret	Hepatitis C, Chronic	glecaprevir , pibrentasvir	26/07/2017	Single Enantiomer	7	C
Maviret	Hepatitis C, Chronic	glecaprevir, pibrentasvir	26/07/2017	Single Enantiomer	8	C
Vosevi	Hepatitis C, Chronic	sofosbuvir, velpatasvir, voxilaprevi	26/07/2017	Single Enantiomer	8	C

Kisqali	Breast Neoplasms	ribociclib succinate	22/08/2017	Achiral	-	-
Fotivda	Carcinoma, Renal Cell	tivozanib	24/08/2017	Achiral	-	-
Xermelo	Carcinoid Tumor; Neuroendocrine Tumors	telotristat etiprate	17/09/2017	Single Enantiomer	2	C
Bavencio	Neuroendocrine Tumors	avelumab	18/09/2017	Biologic	-	-
Rydapt	Leukemia, Myeloid, Acute; Mastocytosis	midostaurin	18/09/2017	Single Enantiomer	4	C
Tecentriq	Carcinoma, Transitional Cell; Carcinoma, Non-Small-Cell Lung; Urologic Neoplasms; Breast Neoplasms; Small Cell Lung Carcinoma	atezolizumab	20/09/2017	Biologic	-	-
Lutathera	Neuroendocrine Tumors	lutetium (177lu) oxodotreotide	26/09/2017	Biologic	-	-
Dupixent	Dermatitis, Atopic; Prurigo; Esophageal Diseases; Asthma; Sinusitis	dupilumab	26/09/2017	Biologic	-	-
Tookad	Prostatic Neoplasms	padeliporfin di-potassium	10/11/2017	Biologic	-	-
Tremfya	Psoriasis	guselkumab	10/11/2017	Biologic	-	-
Zejula	Fallopian Tube Neoplasms; Peritoneal Neoplasms; Ovarian Neoplasms	niraparib (tosilate monohydrate)	16/11/2017	Single Enantiomer	1	C
Prevymis	Cytomegalovirus Infections	letermovir	8/01/2018	Single Enantiomer	1	C
Ocrevus	Multiple Sclerosis	ocrelizumab	8/01/2018	Biologic	-	-
Adynovi	Hemophilia A	rurioctocog alfa pegol	8/01/2018	Biologic	-	-
Fasenra	Asthma	benralizumab	8/01/2018	Biologic	-	-
Ozempic	Diabetes Mellitus	semaglutide	8/02/2018	Biologic	-	-
Crysvita	Hypophosphatemia, Familial; Hypophosphatemic	burosumab	19/02/2018	Biologic	-	-

	Rickets, X-Linked Dominant; Osteomalacia					
Hemlibra	Hemophilia A	emicizumab	23/02/2018	Biologic	-	-
Steglatro	Diabetes Mellitus, Type 2	ertugliflozin l-pyroglutamic acid	21/03/2018	Single Enantiomer	6	C
Shingrix	Herpes Zoster	recombinant varicella zoster virus glycoprotein e	21/03/2018	Biologic	-	-
Lokelma	Hyperkalemia	sodium zirconium cyclosilicate	22/03/2018	Achiral	-	-
Lamzedo	alpha-Mannosidosis	velmanase alfa	23/03/2018	Biologic	-	-
Segluromet	Diabetes Mellitus, Type 2	ertugliflozin l-pyroglutamic acid , metformin hydrochloride	23/03/2018	Single Enantiomer	6	C
Steglujan	Diabetes Mellitus, Type 2	ertugliflozin l-pyroglutamic acid , sitagliptin phosphate monohydrate	23/03/2018	Single Enantiomer	6	C
Alofisel	Rectal Fistula	darvadstrocel	23/03/2018	Biologic	-	-
Alpivab	Influenza, Human	peramivir	13/04/2018	Single Enantiomer	5	C
Mylotarg	Leukemia, Myeloid, Acute	gemtuzumab ozogamicin	19/04/2018	Biologic	-	-
Rubraca	Ovarian Neoplasms	rucaparib camsylate	23/05/2018	Single Enantiomer	2	C
Biktarvy	HIV Infections	bictegravir , emtricitabine, tenofovir alafenamide, fumarate	21/06/2018	Single Enantiomer	3	C
Tegsedi	Amyloidosis	inotersen sodium	6/07/2018	Biologic	-	-
Aimovig	Migraine Disorders	erenumab	26/07/2018	Biologic	-	-
Rxulti	Schizophrenia	brexpiprazole	26/07/2018	Achiral	-	-
Myalepta	Lipodystrophy, Familial Partial	metreleptin	29/07/2018	Biologic	-	-
Kymriah	Precursor B-Cell Lymphoblastic Leukemia-Lymphoma; Lymphoma, Large B-Cell, Diffuse	tisagenlecleucel	22/08/2018	Biologic	-	-

Yescarta	Lymphoma, Follicular; Lymphoma, Large B-Cell, Diffuse	axicabtagene ciloleucel	23/08/2018	Biologic	-	-
Mepsevii	Mucopolysaccharidosis VII	vestronidase alfa	23/08/2018	Biologic	-	-
Onpattro	Amyloidosis, Familial	patisiran sodium	27/08/2018	Biologic	-	-
Cablivi	Purpura, Thrombotic Thrombocytopenic	caplacizumab	30/08/2018	Biologic	-	-
Nerlynx	Breast Neoplasms	neratinib	31/08/2018	Achiral	-	-
Ilumetr	Psoriasis	tildrakizumab	17/09/2018	Biologic	-	-
Braftovi	Melanoma; Colorectal Neoplasms	encorafenib	19/09/2018	Single Enantiomer	1	C
Mektovi	Melanoma	binimetinib	20/09/2018	Achiral	-	-
Xerava	Infection; Bacterial Infections	eravacycline	20/09/2018	Single Enantiomer	4	C
Imfinzi	Carcinoma, Non-Small-Cell Lung	durvalumab	21/09/2018	Biologic	-	-
Verzenio	Breast Neoplasms	abemaciclib	26/09/2018	Achiral	-	-
Symkevi	Cystic Fibrosis	tezacaftor, ivacaftor	31/10/2018	Achiral	-	-
Emgality	Migraine Disorders	galcanezumab	14/11/2018	Biologic	-	-
Vabomere	Urinary Tract Infections; Bacteremia; Bacterial Infections; Respiratory Tract Infections; Pneumonia; Pneumonia, Ventilator- Associated	meropenem trihydrate, vaborbactam	20/11/2018	Single Enantiomer	2	C
Alunbrig	Carcinoma, Non-Small-Cell Lung	brigatinib	22/11/2018	Achiral	-	-
Poteligeo	Sezary Syndrome; Mycosis Fungoides	mogamulizumab	22/11/2018	Biologic	-	-
Delstrigo	HIV Infections	doravirine , lamivudine, tenofovir disoproxil fumarate	22/11/2018	Achiral	-	-

Pifeltra	HIV Infections	doravirine	22/11/2018	Achiral	-	-
Jivi	Hemophilia A	damoctocog alfa pegol	22/11/2018	Biologic	-	-
Takhzyro	Angioedemas, Hereditary	lanadelumab	22/11/2018	Biologic	-	-
Luxturna	Leber Congenital Amaurosis; Retinitis Pigmentosa	voretigene neparvovec	22/11/2018	Biologic	-	-
Dengvaxia	Dengue	chimeric yellow fever dengue virus serotype 1 (live, attenuated), chimeric yellow fever dengue virus serotype 2 (live, attenuated), chimeric yellow fever dengue virus serotype 3 (live, attenuated), chimeric yellow fever dengue virus serotype 4 (live, attenuated)	12/12/2018	Biologic	-	-
GHRVVELIN (previously Macimorelin Aeterna Zentaris)	Diagnostic Techniques, Endocrine	macimorelin acetate	11/01/2019	Single Enantiomer	2	C
Erleada	Prostatic Neoplasms	apalutamide	14/01/2019	Achiral	-	-
Besremi	Polycythemia Vera	ropeginterferon alfa-2b	15/02/2019	Biologic	-	-
Mulpleo	Thrombocytopenia	lusutrombopag	18/02/2019	Single Enantiomer	1	C
Rizmoic	Constipation	naldemedine tosilate	18/02/2019	Single Enantiomer	4	C
Ajovy	Migraine Disorders	fremanezumab	28/03/2019	Biologic	-	-
Vizimpro	Carcinoma, Non-Small-Cell Lung	dacomitinib monohydrate	2/04/2019	Achiral	-	-
Zynquista	Diabetes Mellitus, Type 1	sotagliflozin	26/04/2019	Single Enantiomer	5	C
Ondexxya	Drug-Related Side Effects and Adverse Reactions	andexanet alfa	26/04/2019	Biologic	-	-
Skyrizi	Psoriasis; Arthritis, Psoriatic	risankizumab	26/04/2019	Biologic	-	-
Palynziq	Phenylketonurias	pegvaliase	3/05/2019	Biologic	-	-
Waylivra	Hyperlipoproteinemia Type I	volanesorsen sodium	3/05/2019	Biologic	-	-

Lorviqua	Carcinoma, Non-Small-Cell Lung	lorlatinib	6/05/2019	Single Enantiomer	1	C
Zynteglo	beta-Thalassemia	autologous cd34+ cell enriched population that contains hematopoietic stem cells transduced with lentiglobin bb305 lentiviral vector encoding the beta-a-t87q-globin gene	29/05/2019	Biologic	-	-
Talzenna	Breast Neoplasms	talazoparib	20/06/2019	Single Enantiomer	2	C
Doptelet	Thrombocytopenia	avatrombopag maleate	20/06/2019	Achiral	-	-
Esperoct	Hemophilia A	turoctocog alfa pegol	20/06/2019	Biologic	-	-
Libtayo	Carcinoma, Squamous Cell	cemiplimab	28/06/2019	Biologic	-	-
Ultomiris	Hemoglobinuria, Paroxysmal	ravulizumab	2/07/2019	Biologic	-	-
Giapreza	Hypotension; Shock	angiotensin ii acetate	23/08/2019	Biologic	-	-
Vitrakvi	Abdominal Neoplasms	larotrectinib sulfate	19/09/2019	Single Enantiomer	2	C
Trogarzo	HIV Infections	ibalizumab	26/09/2019	Biologic	-	-
Xospata	Leukemia, Myeloid, Acute	gilteritinib fumarate	24/10/2019	Achiral	-	-
Ervebo	Hemorrhagic Fever, Ebola	recombinant vesicular stomatitis virus (strain indiana) with a deletion of the envelope glycoprotein, replaced with the zaire ebolavirus (strain kikwit 1995) surface glycoprotein	11/11/2019	Biologic	-	-
Rhokiinsa	Glaucoma, Open-Angle; Ocular Hypertension	netarsudil	19/11/2019	Single Enantiomer	1	C
Evenity	Osteoporosis	romosozumab	9/12/2019	Biologic		
Quofenix	Community-Acquired Infections	delafloxacin meglumine	16/12/2019	Single Enantiomer	4	C
Rinvoq	Arthritis, Rheumatoid	upadacitinib	16/12/2019	Single Enantiomer	2	C
Tavlesse	Thrombocytopenia	fostamatinib disodium	9/01/2020	Achiral	-	-
Isturisa	Cushing Syndrome	osilodrostat phosphate	9/01/2020	Single Enantiomer	1	C

Mayzent	Multiple Sclerosis, Relapsing-Remitting	siponimod fumaric acid	13/01/2020	Achiral	-	-
Polivy	Lymphoma, B-Cell	polatuzumab vedotin	16/01/2020	Biologic	-	-
Sunosi	Narcolepsy; Sleep Apnea, Obstructive	solriamfetol hydrochloride	16/01/2020	Single Enantiomer	1	C
Recarbrio	Gram-Negative Bacterial Infections	imipenem monohydrate, cilastatin sodium, relebactam monohydrate	13/02/2020	Single Enantiomer	3	C
Beovu	Wet Macular Degeneration	brolocizumab	13/02/2020	Biologic	-	-
Givlaari	Porphyrias, Hepatic	givosiran	2/03/2020	Biologic	-	-
Nubeqa	Prostatic Neoplasms, Castration-Resistant	darolutamide	27/03/2020	Biologic	-	-
Nustendi	Hypercholesterolemia; Dyslipidemias	bempedoic acid, ezetimibe	27/03/2020	Achiral	-	-
Staquis	Dermatitis, Atopic	crisaborole	27/03/2020	Achiral	-	-
Vaxchora	Cholera	vibrio cholerae, strain cvd 103-hgr, live	1/04/2020	Biologic	-	-
Nilemdo	Hypercholesterolemia; Dyslipidemias	bempedoic acid	1/04/2020	Achiral	-	-
Zolgensma	Muscular Atrophy, Spinal	onasemnogene abeparvovec	18/05/2020	Biologic	-	-
Sarclisa	Multiple Myeloma	isatuximab	30/05/2020	Biologic	-	-
Daurismo	Leukemia, Myeloid, Acute	glasdegib maleate	26/06/2020	Single Enantiomer	2	C
Mvabea	Hemorrhagic Fever, Ebola	recombinant modified vaccinia ankara bavarian nordic virus encoding the: ebola virus zaire (zebov) mayinga strain glycoprotein (gp); ebola virus sudan gulu strain gp; ebola virus tai forest strain nucleoprotein and the marburg virus musoke strain gp	1/07/2020	Biologic	-	-
Zabdeno	Hemorrhagic Fever, Ebola	recombinant adenovirus type 26 (ad26) encoding the glycoprotein (gp) of the ebola virus zaire (zebov) mayinga strain	1/07/2020	Biologic	-	-
Veklury	COVID-19 virus infection	remdesivir	3/07/2020	Single Enantiomer	6	1 P, 5 C

Xenleta	Pneumonia, Bacterial; Community-Acquired Infections	lefamulin acetate	27/07/2020	Single Enantiomer	11	C
Rozlytrek	Cancer; Carcinoma, Non- Small-Cell Lung	entrectinib	31/07/2020	Achiral	-	-
Hepcludex	Hepatitis D, Chronic	bulevirtide acetate	31/07/2020	Biologic	-	-
Dovprela	Tuberculosis, Multidrug- Resistant	pretomanid	31/07/2020	Single Enantiomer	1	C
Kaftrio	Cystic Fibrosis	ivacaftor, tezacaftor, elexacaftor	21/08/2020	Achiral	-	-
Blenrep	Multiple Myeloma	belantamab mafodotin	25/08/2020	Biologic	-	-
Idefirix	Desensitization, Immunologic; Kidney Transplantation	imlifidase	25/08/2020	Biologic	-	-
Ayvakyt	Gastrointestinal Stromal Tumors	avapritinib	24/09/2020	Single Enantiomer	1	C
Jyseleca	Arthritis, Rheumatoid	filgotinib maleate	24/09/2020	Achiral	-	-
Adakveo	Anemia, Sickle Cell	crizanlizumab	28/10/2020	Biologic	-	-
Calquence	Leukemia, Lymphocytic, Chronic, B-Cell	acalabrutinib	5/11/2020	Single Enantiomer	1	C
Supemtek	Influenza, Human	influenza a virus subtype h1n1 haemagglutinin, recombinant, influenza a virus subtype h3n2 haemagglutinin, recombinant, influenza b virus victoria lineage haemagglutinin, recombinant, influenza b virus yamagata lineage haemagglutinin, recombinant	16/11/2020	Biologic	-	-
Nyxthracis (previously Obiltoxaxim ab SFL)	Anthrax	nyxthracis	18/11/2020	Biologic	-	-
Oxlumo	Hyperoxaluria, Primary	lumasiran sodium	19/11/2020	Biologic	-	-
Tecartus	Lymphoma, Mantle-Cell	autologous peripheral blood t cells cd4 and cd8 selected and cd3 and cd28 activated transduced with retroviral vector expressing	14/12/2020	Biologic	-	-

		anti-cd19 cd28/cd3-zeta chimeric antigen receptor and cultured (brexucabtagene autoleucel)				
Vocabria	HIV Infections	cabotegavir sodium, cabotegravir	17/12/2020	Single Enantiomer	2	C
Libmeldy	Leukodystrophy, Metachromatic	atidarsagene autotemcel	17/12/2020	Biologic	-	-
Phesgo	Breast Neoplasms	pertuzumab, trastuzumab	21/12/2020	Biologic	-	-
Comirnaty	COVID-19 virus infection	single-stranded, 5'-capped messenger rna produced using a cell-free in vitro transcription from the corresponding dna templates, encoding the viral spike (s) protein of sars-cov-2	21/12/2020	Biologic	-	-
Spikevax	COVID-19 virus infection	cx-024414 (single-stranded, 5'-capped messenger rna (mrna) produced using a cell-free in vitro transcription from the corresponding dna templates, encoding the viral spike (s) protein of sars-cov-2)	6/01/2021	Biologic	-	-
Elzonris	Lymphoma	tagraxofusp	7/01/2021	Biologic	-	-
Xofluza	Influenza, Human	baloxavir marboxil	7/01/2021	Single Enantiomer	2	C
Enhertu	Breast Neoplasms	trastuzumab deruxtecan	18/01/2021	Biologic	-	-
Vaxzevria	COVID-19 virus infection	chadox1-sars-cov-2	29/01/2021	Biologic	-	-
Rukobia	HIV Infections	fostemsavir trometamol	4/02/2021	Achiral	-	-
Inrebic	Myeloproliferative Disorders; Primary Myelofibrosis	fedratinib dihydrochloride monohydrate	8/02/2021	Achiral	-	-
Lumoxiti	Leukemia, Hairy Cell	moxetumomab pasudotox	8/02/2021	Biologic	-	-
Retsevmo	Carcinoma, Non-Small-Cell Lung; Thyroid Neoplasms	selpercatinib	11/02/2021	Achiral	-	-
Tukysa	Breast Neoplasms; Neoplasm Metastasis	tucatinib	11/02/2021	Achiral	-	-
Jcovden	COVID-19 virus infection	adenovirus type 26 encoding the sars-cov-2 spike glycoprotein (ad26.cov2-s)	11/03/2021	Biologic	-	-
Nexpovio	Multiple Myeloma	selinexor	26/03/2021	Achiral	-	-

Pemazyre	Cholangiocarcinoma	pemigatinib	26/03/2021	Achiral	-	-
Byfavo	Conscious Sedation	remimazolam	26/03/2021	Single Enantiomer	1	C
Evrystdi	Muscular Atrophy, Spinal	risdiplam	26/03/2021	Achiral	-	-
Vazkepa	Dyslipidemias	icosapent ethyl	26/03/2021	Achiral	-	-
Sogroya	Growth	somapacitan	31/03/2021	Biologic	-	-
Jemperli	Endometrial Neoplasms	dostarlimab	21/04/2021	Biologic	-	-
Copiktra	Leukemia, Lymphocytic, Chronic, B-Cell; Lymphoma, Follicular	duvelisib	19/05/2021	Single Enantiomer	1	C
Drovelis	Contraceptives, Oral	drospirenone, estetrol monohydrate	19/05/2021	Single Enantiomer	7	C
Lydisilka	Contraceptives, Oral	estetrol monohydrate , drospirenone	19/05/2021	Single Enantiomer	7	C
Koselugo	Neurofibromatosis 1	selumetinib sulfate	17/06/2021	Achiral	-	-
Evkeeza	Hypercholesterolemia	evinacumab	17/06/2021	Biologic	-	-
Enspryng	Neuromyelitis Optica	satralizumab	24/06/2021	Biologic	-	-
Skysona	Adrenoleukodystrophy	elivaldogene autotemcel	16/07/2021	Biologic	-	-
Imcivree	Obesity	setmelanotide	16/07/2021	Biologic	-	-
Verquvo	Heart Failure	vericiguat	16/07/2021	Achiral	-	-
Klisyri	Keratosis, Actinic	tirbanibulin	16/07/2021	Achiral	-	-
Ryeqo	Leiomyoma	relugolix , norethisterone acetate, estradiol hemihydrate	16/07/2021	Achiral	-	-
Bylvay	Cholestasis, Intrahepatic	odevixibat	16/07/2021	Single Enantiomer	2	C
Abecma	Multiple Myeloma; Neoplasms; Cancer; Neoplasms, Plasma Cell; Hemostatic Disorders; Vascular Diseases; Cardiovascular Diseases;	idecabtagene vicleucel	18/08/2021	Biologic	-	-

	Paraproteinemias; Blood Protein Disorders; Hematologic Diseases; Hemic and Lymphatic Diseases; Hemorrhagic Disorders; Infectious Mononucleosis; Lymphoproliferative Disorders; Immunoproliferative Disorders; Immune System Diseases					
Evrenzo	Anemia; Kidney Failure, Chronic	roxadustat	18/08/2021	Achiral	-	-
Bimzelx	Psoriasis	bimekizumab	20/08/2021	Biologic	-	-
Minjuvi	Lymphoma, Large B-Cell, Diffuse	tafasitamab	26/08/2021	Biologic	-	-
Voxzogo	Achondroplasia	vosoritide	26/08/2021	Biologic	-	-
Regkirona	COVID-19 virus infection	regdanvimab	12/11/2021	Biologic	-	-
Ronapreve	COVID-19 virus infection	casirivimab, imdevimab	12/11/2021	Biologic	-	-
Gavreto	Carcinoma, Non-Small-Cell Lung	pralsetinib	18/11/2021	Single Enantiomer	1	C
Qinlock	Gastrointestinal Stromal Tumors	ripretinib	18/11/2021	Achiral	-	-
Trodelyv	Breast Neoplasms; Triple Negative Breast Neoplasms	sacituzumab govitecan	22/11/2021	Biological	-	-
Brukinsa	Waldenstrom Macroglobulinemia	zanubrutinib	22/11/2021	Single Enantiomer	1	C
Artesunate Amivas	Malaria	artesunate	22/11/2021	Single Enantiomer	8	C

Rybrevant	Carcinoma, Non-Small-Cell Lung	amivantamab	9/12/2021	Biologic	-	-
Cibinqo	Dermatitis, Atopic	abrocitinib	9/12/2021	Achiral	-	-
Vaxneuvance	Pneumococcal Infections	pneumococcal polysaccharide conjugate vaccine (adsorbed)	13/12/2021	Biologic	-	-
Xevudy	COVID-19 virus infection	sotrovimab	17/12/2021	Biologic	-	-
Nuvaxovid	COVID-19 virus infection	sars-cov-2 recombinant spike protein	20/12/2021	Biologic	-	-
Lumykras	Carcinoma, Non-Small-Cell Lung	sotorasib	6/01/2022	Single Enantiomer	1	C
Tecovirimat SIGA	Poxviridae Infections; Cowpox; Monkeypox; Vaccinia; Smallpox	tecovirimat	6/01/2022	Single Enantiomer	6	C
Voraxaze	Metabolic Side Effects of Drugs and Substances	glucarpidase	11/01/2022	Biologic	-	-
Skytrofa	Growth and Development	lonapegsomatropin	11/01/2022	Biologic	-	-
Tavneos	Microscopic Polyangiitis; Wegener Granulomatosis	avacopan	11/01/2022	Single Enantiomer	2	C
Vyepti	Migraine Disorders	eptinezumab	24/01/2022	Biologic	-	-
Paxlovid	COVID-19 virus infection	nirmatrelvir , ritonavir	28/01/2022	Single Enantiomer	6	C
Ngenla	Growth and Development	somatogon	14/02/2022	Biologic	-	-
Oxbryta	Anemia; Anemia, Hemolytic; Anemia, Sickle Cell	voxelotor	14/02/2022	Achiral	-	-
Saphnelo	Lupus Erythematosus, Systemic	anifrolumab	14/02/2022	Biologic	-	-
Apexxnar	Pneumococcal Infections	pneumococcal polysaccharide serotype 1, pneumococcal polysaccharide serotype 3, pneumococcal polysaccharide serotype 4, pneumococcal polysaccharide serotype 5, pneumococcal polysaccharide serotype 6a, pneumococcal polysaccharide serotype 6b, pneumococcal polysaccharide serotype 7f, pneumococcal polysaccharide serotype 8, pneumococcal	14/02/2022	Biologic	-	-

		polysaccharide serotype 9v, pneumococcal polysaccharide serotype 10a, pneumococcal polysaccharide serotype 11a, pneumococcal polysaccharide serotype 12f, pneumococcal polysaccharide serotype 14, pneumococcal polysaccharide serotype 15b, pneumococcal polysaccharide serotype 18c, pneumococcal polysaccharide serotype 19a, pneumococcal polysaccharide serotype 19f, pneumococcal polysaccharide serotype 22f, pneumococcal polysaccharide serotype 23f, pneumococcal polysaccharide serotype 33f				
Tepmetko	Carcinoma, Non-Small-Cell Lung	tepotinib hydrochloride monohydrate	16/02/2022	Achiral	-	-
Kerendia	Renal Insufficiency, Chronic; Diabetes Mellitus, Type 2	finerenone	16/02/2022	Single Enantiomer	1	C
Evusheld	COVID-19 virus infection	tixagevimab, cilgavimab	25/03/2022	Biologic	-	-
Kimmtrak	Uveal Neoplasms	tebentafusp	1/04/2022	Biologic	-	-
Breyanzi	Lymphoma, Large B-Cell, Diffuse; Lymphoma, Follicular; Mediastinal Neoplasms	cd19-directed genetically modified autologous cell-based product consisting of purified cd8+ t-cells (cd8+ cells), cd19-directed genetically modified autologous cell-based product consisting of purified cd4+ t cells (cd4+ cells)	4/04/2022	Biologic	-	-
Padcev	Carcinoma, Transitional Cell; Urologic Neoplasms	enfortumab vedotin	13/04/2022	Biologic	-	-
Vydura	Migraine Disorders	rimegepant	25/04/2022	Single Enantiomer	3	C
Kapruvia	Pruritus	difelikefalin	25/04/2022	Biologic	-	-
Uplizna	Neuromyelitis Optica	inebilizumab	25/04/2022	Biologic	-	-
Quviviq	Sleep Initiation and Maintenance Disorders	daridorexant hydrochloride	29/04/2022	Single Enantiomer	1	C
Carvykti	Multiple Myeloma	ciltacabtagene autoleucl	25/05/2022	Biologic	-	-
Lunsumio	Lymphoma, Follicular	mosunetuzumab	3/06/2022	Biologic	-	-
Yselty	Leiomyoma	linzagolix choline	14/06/2022	Achiral	-	-

Tabrecta	Carcinoma, Non-Small-Cell Lung	capmatinib dihydrochloride monohydrate	20/06/2022	Achiral	-	-
Xenpozyme	Acid sphingomyelinase deficiency (ASMD) type A/B or type B	olipudase alfa	24/06/2022	Biologic	-	-
COVID-19 Vaccine Valneva	COVID-19 virus infection	sars-cov-2 virus (inactivated) wuhan strain hcov-19 / italy / inmi1-isl / 2020	24/06/2022	Biologic	-	-
Upstaza	Amino Acid Metabolism, Inborn Errors	eladocagene exuparvovec	18/07/2022	Biologic		
Zokinvy	Progeria; Laminopathies	lonafarnib	18/07/2022	Single Enantiomer	1	C
Vyvgart	Myasthenia Gravis	efgartigimod alfa	10/08/2022	Biologic	-	-
Rayvow	Migraine Disorders	lasmiditan succinate	17/08/2022	Achiral	-	-
Sunlenca	HIV Infections	lenacapavir sodium	17/08/2022	Single Enantiomer	3	C
Tecvayli	Multiple Myeloma	teclistamab	23/08/2022	Biologic	-	-
Roctavian	Hemophilia A	valoctocogene roxaparvovec	24/08/2022	Biologic	-	-
Opdualag	Melanoma	nivolumab, relatlimab	15/09/2022	Biologic	-	-
Amvuttra	Amyloid Neuropathies, Familial	vutrisiran sodium	15/09/2022	Biologic	-	-
Mounjaro	Diabetes Mellitus, Type 2	tirzepatide	15/09/2022	Biologic	-	-
Nulibry	Metal Metabolism, Inborn Errors	fosdenopterin hydrobromide dihydrate	15/09/2022	Single Enantiomer	4	C
Lupkynis	Lupus Nephritis	voclosporin	15/09/2022	Single Enantiomer	12	C
Vabysmo	Wet Macular Degeneration; Macular Edema; Diabetes Complications	faricimab	15/09/2022	Biologic	-	-
Tezspire	Asthma	tezepelumab	19/09/2022	Biologic	-	-

Beyfortus	Respiratory syncytial virus	nirsevimab	31/10/2022	Biologic	-	-
Pyrukynd	Genetic Diseases, Inborn; Anemia, Hemolytic	mitapivat sulfate	9/11/2022	Achiral	-	-
Livtencity	Cytomegalovirus Infections	maribavir	9/11/2022	Single Enantiomer	4	C
VidPrevtn Beta	COVID-19 virus infection	sars-cov-2 prefusion spike delta tm protein, recombinant (b.1.351 strain)	10/11/2022	Biologic	-	-
Enjaymo	Hemolysis; Anemia, Hemolytic, Autoimmune	sutimlimab	15/11/2022	Biologic	-	-
Qdenga	Dengue	dengue virus, serotype 2, expressing dengue virus, serotype 1, surface proteins, live, attenuated, dengue virus, serotype 2, expressing dengue virus, serotype 3, surface proteins, live, attenuated, dengue virus, serotype 2, expressing dengue virus, serotype 4, surface proteins, live, attenuated, dengue virus, serotype 2, live, attenuated	5/12/2022	Biologic	-	-
Pluvicto	Prostatic Neoplasms, Castration-Resistant	lutetium (177lu) vipivotide tetraxetan	9/12/2022	Biologic	-	-
Spevigo	Psoriasis	spesolimab	9/12/2022	Biologic	-	-
Locametz	Radionuclide Imaging	gozetotide	9/12/2022	Biologic	-	-
Eladynos	Osteoporosis, Postmenopausal; Osteoporosis	abaloparatide	12/12/2022	Biologic	-	-
Ebvallo	Lymphoproliferative Disorders	tabelecleucel	16/12/2022	Biologic	-	-
Zynlonta	Lymphoma, Large B-Cell, Diffuse; Lymphoma, B-Cell	loncastuximab tesirine	20/12/2022	Biologic	-	-
Imjudo	Carcinoma, Hepatocellular	tremelimumab	20/02/2023	Biologic	-	-
Tremelimum ab AstraZeneca	Carcinoma, Non-Small-Cell Lung	tremelimumab	20/02/2023	Biologic	-	-
Hemgenix	Hemophilia B	etranacogene dezaparvovec	20/02/2023	Biologic	-	-

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