

Supplementary data: Table 1 – FDA-approved drugs

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
1991 New molecular entities = 28					
1 Ondansetron HCl (Zofran)	Novartis	5-HT ₃ receptor antagonist	Nausea and vomiting caused by radiotherapy, anesthesia, surgery or cytotoxic chemotherapy drugs	01/04/1991	P
2 Gallium nitrate (Ganite)	Chapter 7 Trustee	Bone-resorption inhibitor	Hypercalcemia of malignancy	01/17/1991	P, O
3 Ramipril (Altace)	King Pharms	Angiotensin-converting enzyme (ACE) inhibitor	Hypertension	01/28/1991	S
4 Succimer (Chemet)	Recordati Rare	Analog of dimercaprol, binds to heavy metals and forms a water-soluble complex	Poisoning by lead and other heavy metals	01/30/1991	P, O
5 Etodolac (Lodine)	Wyeth Pharms	Cyclooxygenase-2 (COX-2) inhibitor	Osteoarthritis, rheumatoid arthritis and control acute pain	01/31/1991	S
6 Doxacurium chloride (Nuromax)	AbbVie	Neuromuscular-blocking drug or skeletal muscle relaxant	Adjunctively in anesthesia for endotracheal intubation or to facilitate mechanical ventilation	03/07/1991	S
7 Fludarabine phosphate (Fludara)	Genzyme Corp	DNA synthesis inhibitor	B-cell chronic lymphocytic leukemia	04/18/1991	P
8 Fosinopril sodium (Monopril)	Bristol-Myers Squibb	Angiotensin-converting enzyme (ACE) inhibitor	Hypertension	05/16/1991	S
9 Benazepril HCl (Lotensin)	Validus Pharms	Angiotensin-converting enzyme (ACE) inhibitor	Hypertension	06/25/1991	S
10 Felodipine (Plendil)	AstraZeneca	Voltage-gated L-type calcium channel stabilizer	Hypertension	07/25/1991	S
11 Foscarnet sodium (Foscavir)	Clinigen Hlthcare	Virus-specific DNA polymerase inhibitor	Cytomegalovirus retinitis in patients with AIDS	09/27/1991	P
12 Didanosine (Videx)	Bristol-Myers Squibb	HIV-1 reverse transcriptase inhibitor	HIV-1 infection	10/09/1991	P
13 Pentostatin (Nipent)	Hospira	Purine analog, irreversible inhibitor of adenosine deaminase	INF α -refractory hairy cell leukemia	10/11/1991	P, O
14 Pravastatin sodium (Pravachol)	Bristol-Myers Squibb	HMG CoA reductase inhibitor	Hypercholesterolemia	10/31/1991	S
15 Ticlopidine HCl (Ticlid)	Roche Palo	Adenosine diphosphate receptor inhibitor	Prevention of strokes	10/31/1991	P
16 Pamidronate disodium (Aredia)	Novartis	Bone-resorption inhibitor	Hypercalcemia of malignancy	10/31/1991	P
17 Clarithromycin (Biaxin)	AbbVie	Binds to 23s rRNA (with nucleotides in domains II and V) and inhibits the protein synthesis in bacteria	Broad range of infections	10/31/1991	P
18 Azithromycin (Zithromax)	Pfizer	Inhibits bacterial protein synthesis by binding to the 50S ribosomal subunit of the bacterial 70S ribosome	Bacterial infections	11/01/1991	P
19 Quinapril HCl (Accupril)	Pfizer Pharms	Angiotensin-converting enzyme (ACE) inhibitor	Hypertension	11/19/1991	S
20 Flumazenil (Romazicon)	Roche	Imidazobenzodiazepine derivative and benzodiazepine receptor antagonist	Reversal of the sedative effects of benzodiazepines	12/20/1991	P
21 Simvastatin (Zocor)	Organon	HMG CoA reductase inhibitor	Hyperlipidemia	12/23/1991	S
22 Cefprozil (Cefzil)	Corden Pharma	β -lactam antibiotic, inhibits bacterial cell wall synthesis by binding to specific PBPs	Mild to moderate infections of upper/lower respiratory tract and uncomplicated skin/skin-structure infections	12/23/1991	S
23 Nabumetone (Relafen)	Smithkline Beecham	Cyclooxygenase-1/2 (COX-1/2) inhibitor	Osteoarthritis and rheumatoid arthritis	12/24/1991	S
24 Histrelin acetate (Supprelin)	Shire	Gonadotropin-releasing hormone (GnRH) agonist	Children with central precocious puberty (CPP)	12/24/1991	P
25 Isosorbide mononitrate (Ismo)	Promius Pharma	Soluble guanylate cyclase stimulator	Acute and chronic angina pectoris, hypertension, and myocardial infarction	12/30/1991	S
26 Sertraline HCl (Zoloft)	Upjohn	Serotonin reuptake inhibitor	Major depressive disorder, obsessive-compulsive disorder, panic disorder, and social anxiety disorder	12/30/1991	S
27 Enoxacin (Penetrex)	Sanofi	Quinolone/fluoroquinolone antibiotic, inhibits bacterial DNA gyrase and topoisomerase IV	Urinary tract infections and gonorrhea	12/31/1991	S
28 Loracarbef (Lorabid)	King Pharms	β -lactam antibiotic, inhibits bacterial cell wall synthesis by binding to specific PBPs	Mild to moderate infections caused by susceptible strains of the designated microorganisms	12/31/1991	S
1991 Biologics license applications = 4					
1 Filgrastim (Neupogen)	Amgen	Recombinant human granulocyte colony-stimulating factor (G-CSF)	Severe neutropenia in patients with non-myeloid malignancies	02/20/1991	N/A
2 Sargramostim (Leukine)	Berlex Labs	Recombinant human granulocyte macrophage colony-stimulating factor (GM-CSF)	Myeloid reconstitution after PBPC/bone marrow transplantation, or with NHL, ALL, HL	03/05/1991	O
3 Aiglucerase (Ceredase)	Genzyme	Modified human β -glucocerebrosidase enzyme	Type 1 Gaucher's disease	04/05/1991	O
4 Beractant (Survanta)	AbbVie	Natural bovine pulmonary surfactant	Respiratory distress syndrome in premature infants	07/01/1991	O

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
1992 New molecular entities = 26					
1 Mivacurium chloride (Mivacron)	AbbVie	Cholinergic receptor inhibitor	Adjunctively in anesthesia for endotracheal intubation or to facilitate mechanical ventilation	01/22/1992	P
2 Temafloxacin HCl (Omniflox)	Abbott	Fluoroquinolone antibiotic	Systemic bacterial infections	01/30/1992	N/A
3 Lomefloxacin HCl (Maxaquin)	Pharmacia	Fluoroquinolone antibiotic	Respiratory tract, genital, urinary, and skin infections	02/21/1992	S
4 Finasteride (Proscar)	Merck & Co	Steroid type II 5 α reductase inhibitor	Benign prostatic hyperplasia	06/19/1992	P
5 Zalcitabine (Hivid)	Roche	Nucleoside analog, HIV-reverse transcriptase inhibitor	HIV infection	06/19/1992	P, O
6 Teniposide (Vumon)	HQ spclt Pharma	Topoisomerase II inhibitor	Refractory childhood acute lymphoblastic leukemia	07/14/1992	P, O
7 Halofantrine HCl (Halfan)	GlaxoSmithKline	Blood schizonticidal antimalarial agent, binds to haemoglobin degrading enzyme unique to the malarial parasites	Malaria	07/24/1992	P, O
8 Bisoprolol fumarate (Zebeta)	Teva	Cardioselective β 1-adrenergic blocking agent	Cardiovascular diseases such as hypertension, coronary heart disease, arrhythmias, ischemic heart diseases, and myocardial infarction after the acute event	07/31/1992	S
9 Cefpodoxime proxetil (Vantin)	Pharmacia & Upjohn	Inhibits bacterial cell wall synthesis by binding PBPs	Mild to moderate infections caused by susceptible strains of the designated microorganisms	08/07/1992	S
10 Masoprocol (Actinex)	Univ AZ Cancer Ctr	5-lipoxygenase inhibitor	Actinic keratoses	09/04/1992	S
11 Itraconazole (Sporanox)	Janssen Pharms	Inhibits the cytochrome P450-dependent synthesis of ergosterol	Fungal infections	09/11/1992	P
12 Desflurane (Suprane)	Baxter Hlthcare	May act on the lipid matrix of the neuronal membrane	Induction and/or maintenance of anesthesia	09/18/1992	S
13 Oxaprozin (Daypro)	Pfizer	Cyclooxygenase-1 (COX-1) inhibitor	Rheumatoid arthritis, osteoarthritis, dysmenorrhea, and to alleviate moderate pain	10/29/1992	S
14 Sotalol HCl (Betapace)	Covis	β 1- and β 2-adrenergic receptor inhibitor	Ventricular arrhythmias, symptomatic atrial fibrillation, and symptomatic atrial flutter	10/30/1992	P, O
15 Gadoteridol (Prohance)	Bracco	Gadolinium-based MRI contrast agent	Imaging of central nervous system	11/16/1992	S
16 Atovaquone (Mepron)	GlaxoSmithKline	Cytochrome bc1 complex (Complex III) inhibitor	<i>Pneumocystis carinii</i> pneumonia	11/25/1992	P, O
17 Desogestrel; Ethinyl estradiol (Desogen)	Organon USA	Progesterone receptor activator; derivative of the natural estrogen estradiol	Contraception	12/10/1992	S
18 Zolpidem tartrate (Ambien)	Sanofi	γ -Aminobutyric-acid type A (GABA-A receptor) stimulator	Insomnia	12/16/1992	S
19 Rifabutin (Mycobutin)	Pfizer	Bacterial RNA polymerase inhibitor	Prophylaxis of disseminated MAC disease in patients with advanced HIV infection	12/23/1992	P, O
20 Sumatriptan succinate (Imitrex)	GlaxoSmithKline	5-HT _{1B/D} receptor agonist	Reduction of vascular inflammation associated with migraines	12/28/1992	P
21 Indium In-111 chloride (Indiclor)	GE Healthcare	Radioactive diagnostic agent	Radiolabeling Satumomab pentetide (OncoScint), Capromab pentetide (ProstaScint) and Ibritumomab tiuxetan (Zevalin)	12/29/1992	S
22 Paroxetine HCl (Paxil)	Apotex Technologies	Serotonin reuptake inhibitor	Major depressive disorder, obsessive-compulsive disorder, social anxiety disorder, panic disorder, posttraumatic stress disorder, generalized anxiety disorder, and premenstrual dysphoric disorder	12/29/1992	S
23 Paclitaxel (Taxol)	HQ Spclt Pharma	Microtubule-stabilizing agent	Advanced ovarian cancer	12/29/1992	P, O
24 Flosequinan (Manoplax)	Boots	Potential Phosphodiesterase 3 (PDE3) inhibitor	Heart failure	12/30/1992	N/A
25 Nedocromil sodium (Tilade)	King Pharms	Mast cell stabilizer	Itching associated with allergic conjunctivitis	12/30/1992	S
26 Terbinafine HCl (Lamisil)	Novartis	Inhibits squalene epoxidase-dependent ergosterol synthesis	Ringworm and fungal nail infections	12/30/1992	S
1992 Biologics license applications = 2					
1 Aldesleukin (Proleukin)	Chiron	Recombinant human interleukin-2	Metastatic renal cell carcinoma	05/05/1992	O
2 Indium In-111 satumomab pentetide (OncoScint)	Cytogen	TAG-72-specific radiolabeled mAb	Imaging of colorectal or ovarian cancer	12/29/1992	O

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Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
1993 New molecular entities = 24					
1 Gadodiamide (Omniscan)	GE Healthcare	Nonionic, low-osmolar gadolinium-based contrast agent	Contrast-enhanced magnetic resonance imaging	01/08/1993	S
2 Cladribine (Leustatin)	Janssen Pharms	Adenosine deaminase inhibitor	Hairy cell leukemia and multiple sclerosis	02/26/1993	S
3 Enoxaparin sodium (Lovenox)	Sanofi	Antithrombin III activator	Deep vein thrombosis (DVT) and pulmonary embolism (PE)	03/29/1993	P
4 Loratadine (Claritin)	Bayer	Histamine H1 receptor antagonist	Allergic rhinitis and urticaria	04/12/1993	S
5 Strontium chloride Sr-89 (Metastron)	Q Biomed	A radiopharmaceutical that concentrates in the bone of invaded tumor	Bone metastasis of tumor induced pain	06/18/1993	P
6 Levomethadyl acetate HCl (Orlaam)	Roxane	μ-opioid receptor agonist	Opioid addiction	07/09/1993	P, O
7 Felbamate (Felbatol)	Mylan Speciality	Dicarbamate derivative, inhibition of voltage-sensitive sodium and calcium channels, modulation of NMDA receptors, and potentiation of GABA transmission	Epilepsy	07/29/1993	P, O
8 Cisapride monohydrate (Propulsid)	Janssen Pharms	5-HT ₄ receptor agonist	Nocturnal heartburn due to gastroesophageal reflux disease	07/29/1993	S
9 Perflubron (Imagent)	Alliance Pharm	Bromine-based particulate contrast agent	Magnetic resonance imaging, computed tomography, and sonography	08/13/1993	P
10 Torsemide (Demadex)	Mylan Speciality	Pyridine-sulfonylurea type loop diuretic	Edema associated with congestive heart failure, renal disease, or hepatic disease	08/23/1993	S
11 Tacrine HCl (Cognex)	Shionogi	Parasympathomimetic, reversible cholinesterase inhibitor	Mild to moderate dementia of the Alzheimer's type	09/09/1993	P
12 Rimantadine HCl (Flumadine)	Sun Pharm	M2 ion channel inhibitor	Influenza virus A infection	09/17/1993	P
13 Lodoxamide tromethamine (Alomide)	Novartis	Mast cell stabilizer	Vernal keratoconjunctivitis, vernal conjunctivitis, and vernal keratitis	09/23/1993	S, O
14 Piperacillin sodium; Tazobactam sodium (Zosyn)	Wyeth Pharms	Broad-spectrum ampicillin derived ureidopenicillin antibiotic; β-lactamase inhibitor	Bacterial infections	10/22/1993	S
15 Levocabastine HCl (Livostin)	Novartis	Histamine H1-receptor antagonist	Allergic conjunctivitis	11/10/1993	P
16 Trimetrexate glucuronate (Neutrexin)	Medimmune Oncology	Folate antagonist, dihydrofolate reductase inhibitor	<i>Pneumocystis carinii</i> pneumonia	12/17/1993	P, O
17 Venlafaxine HCl (Effexor)	Wyeth Pharms	Arylalkanolamine serotonin-norepinephrine reuptake inhibitor	Major depressive disorder	12/28/1993	S
18 Granisetron HCl (Kytril)	Roche	5-HT ₃ receptor agonist	Chemotherapy-induced nausea	12/29/1993	S
19 Risperidone (Risperdal)	Janssen Pharms	5-HT ₂ receptor and dopamine D2 receptor antagonist	Schizophrenia, bipolar mania, irritability associated with autistic disorder	12/29/1993	P
20 Calcipotriene (Dovonex)	Leo Pharma	Synthetic derivative of calcitriol, a form of vitamin D	Psoriasis	12/29/1993	S
21 Perindopril erbumine (Aceon)	Symplmed Pharms	Angiotensin-converting enzyme (ACE) inhibitor	Hypertension	12/30/1993	S
22 Gabapentin (Neurontin)	Upjohn	γ-Aminobutyric-acid (GABA) analog	Seizures	12/30/1993	P
23 Fenofibrate (Lipidil)	AbbVie	Peroxisome proliferator activated receptor α (PPARα) activator	Hyperlipidemia	12/31/1993	S
24 Fluvastatin sodium (Lescol)	Novartis	HMG CoA reductase inhibitor	Hypercholesterolemia and mixed dyslipidemia	12/31/1993	S
1993 Biologics license applications = 4					
1 Antihemophilic factor Recombinant (Kogenate FS)	Bayer	Recombinant coagulation factor VIII	Hemophilia A, von Willebrand disease, and factor XIII deficiency	02/25/1993	O
2 Interferon beta-1b (Betaseron)	Bayer	Recombinant human interferon β-1b	Relapsing multiple sclerosis	07/23/1993	O
3 Aprotinin (Trasylol)	Bayer	Bovine pancreatic trypsin inhibitor	Prophylactic use to reduce perioperative blood loss and the need for blood transfusion	12/29/1993	P, O
4 Dornase alfa (Pulmozyme)	Genentech	Recombinant human DNase I	Cystic fibrosis	12/30/1993	O

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
1994 New molecular entities = 20					
1 Salmeterol xinafoate (Serevent)	GlaxoSmithKline	β2-adrenergic agonist	Asthma, prevention of exercise-induced bronchospasm, maintenance treatment of chronic obstructive pulmonary disease	02/04/1994	P
2 Budesonide (Rhinocort)	Astrazeneca	Glucocorticoid	Asthma, the treatment of various skin disorders, allergic rhinitis and ulcerative colitis	02/14/1994	S
3 Rocuronium bromide (Zemuron)	Organon USA	Neuromuscular blocker or muscle relaxant	Adjunctively in anesthesia for endotracheal intubation or to facilitate mechanical ventilation	03/17/1994	S
4 Acrivastine; Pseudoephedrine HCl (Semprex-D)	Auxilium Pharms	Histamine H1 receptor antagonist; α/β-adrenergic receptors agonist	Seasonal allergic rhinitis	03/25/1994	S
5 Iobenguane sulfate I-131	Pharmalucence	Radiopharmaceutical	Location of pheochromocytomas and neuroblastomas	03/25/1994	P
6 Tacrolimus (Prograf)	Astellas	Macrolide immunosuppressant produced by <i>Streptomyces tsukubaensis</i>	Prophylaxis of organ rejection in patients receiving allogeneic liver transplants, kidney transplants, heart transplants	04/08/1994	P, O
7 Indium In-111 pentetreotide kit (Octreoscan)	Curium	Radioactive diagnostic agent	Location of metastatic neuroblastomas	06/02/1994	P
8 Stavudine (Zerit)	Bristol-Myers Squibb	HIV reverse transcriptase inhibitor	HIV-1 infection	06/24/1994	P
9 Famciclovir (Famvir)	Novartis	Viral DNA polymerase inhibitor	Recurrent episodes of orolabial or genital herpes in HIV-infected adults	06/29/1994	S
10 Cysteamine bitartrate (Cystagon)	Mylan	Cystine-depleting agent	Corneal cystine crystal accumulation in patients with cystinosis	08/15/1994	P, O
11 Fludeoxyglucose F-18	Downstate Clincl	Positron emitting radiopharmaceutical	Positron emission tomography (PET) imaging	08/19/1994	P
12 Technetium Tc-99m bismate kit (Neurolite)	Lantheus Medcl	Radioactive diagnostic agent	Localization of neuroendocrine tumors bearing somatostatin receptors	11/23/1994	S
13 Fluvoxamine maleate (Luvox)	Solvay	Serotonin reuptake inhibitor	Obsessive-compulsive disorder	12/05/1994	S
14 Dorzolamide HCl (Trusopt)	Merck & Co	Carbonic anhydrase II (CA-II) inhibitor	Elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma	12/09/1994	P
15 Nefazodone HCl (Serzone)	Bristol-Myers Squibb	5-HT ₂ receptor agonist	Depression	12/22/1994	S
16 Dalteparin sodium (Fragmin)	Pfizer	Increasing the activity of antithrombin III (AT-III)	Thromboprophylaxis in general/abdominal surgery	12/22/1994	S
17 Vinorelbine tartrate (Navelbine)	Pierre Fabre	Microtubule-destabilizing agent	Non-small-cell lung cancer (NSCLC)	12/23/1994	P
18 Lamotrigine (Lamictal)	GlaxoSmithKline	Presynaptic neuronal membranes stabilizer and glutamate release inhibitor	Epilepsy and bipolar disorder	12/27/1994	P
19 Spirapril HCl (Renormax)	Schering	Angiotensin-converting enzyme (ACE) inhibitor	Hypertension	12/29/1994	S
20 Rimexolone (Vexol)	Eyevance	Glucocorticoid receptor agonist	Eye inflammation caused by infections, injury, surgery, or other conditions	12/30/1994	P
1994 Biologics license applications = 3					
1 Pegaspargase (Oncaspar)	Sigma Tau	<i>Escherichia coli</i> -derived L-asparaginase	Pediatric acute lymphoblastic leukaemia	02/01/1994	O
2 Imiglucerase (Cerezyme)	Genzyme	Recombinant human β-glucocerebrosidase enzyme	Type 1 Gaucher's disease	05/23/1994	O
3 Abciximab (Reopro)	Centocor	anti-glycoprotein IIb/IIIa receptor mAb	Prevention of cardiac ischemic complications in patients undergoing percutaneous coronary intervention	12/22/1994	N/A

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
1995 New molecular entities = 29					
1 Nisoldipine (Sular)	Covis	Calcium channel antagonist	Hypertension	02/02/1995	S
2 Tramadol HCl (Ultram)	Janssen Pharms	μ-opioid receptor agonist	Moderate to severe pain	03/03/1995	S
3 Metformin HCl (Glucophage)	Emd Serono	Decreasing glucose production by the liver	Type 2 diabetes	03/03/1995	P
4 Losartan potassium (Cozaar)	Organon	Angiotensin II receptor type 1 (AT1) antagonist	Hypertension	04/14/1995	S
5 Nalmefene HCl (Revex)	Eurohlth Intl Sarl	μ- and δ-opioid antagonist	Reversal of opioid drug effects	04/17/1995	S
6 Moexipril HCl (Univasc)	UCB Inc	Angiotensin-converting enzyme (ACE) inhibitor	Hypertension	04/19/1995	S
7 Mycophenolate mofetil (Cellcept)	Roche Palo	Inosine-5'-monophosphate dehydrogenase inhibitor	Prophylaxis of organ rejection in recipients of allogeneic kidney, heart, or liver transplants	05/03/1995	P
8 Iopromide (Ultravist 150)	Bayer	Non-ionic X-ray contrast agent	Angiography and computed tomography imaging	05/10/1995	S
9 Lansoprazole (Prevacid)	Takeda	Proton pump inhibitor	Acid-reflux disorders (GERD), peptic ulcer disease, <i>H. pylori</i> eradication, and prevention of gastrointestinal bleeds with NSAID use	05/10/1995	S
10 Dexrazoxane HCl (Zincard)	Pfizer	DNA topoisomerase II inhibitor and iron ions chelator	Doxorubicin-caused cardiomyopathy in patients with breast cancer	05/26/1995	P, O
11 Sevoflurane (Ultane)	AbbVie	Reduction in junctional conductance by decreasing gap junction channel opening times and increasing gap junction channel closing times	Induction and maintenance of general anesthesia	06/07/1995	S
12 Dirithromycin (Dynabac)	Lilly Res Labs	Inhibits bacterial protein synthesis by binding to the 50S ribosomal subunit of the bacterial 70S ribosome	Bacterial infections in respiratory system and skin	06/19/1995	S
13 Acarbose (Precose)	Bayer	Pancreatic α-amylase and membrane-bound intestinal α-glucosidase hydrolase enzymes inhibitor	Type 2 diabetes	09/06/1995	S
14 Azelaic acid (Azelex)	Almirall	May inhibit the cellular protein synthesis in bacteria	Mild to moderate inflammatory acne vulgaris	09/13/1995	S
15 Carvedilol (Coreg)	Woodward	α1- and β-adrenergic receptor inhibitor	Mild to severe heart failure	09/14/1995	S
16 Epoprostenol sodium (Flolan)	GlaxoSmithKline	Prostaglandin	Pulmonary arterial hypertension	09/20/1995	P, O
17 Alendronate sodium (Fosamax)	Merck & Co	Osteoclast-mediated bone-resorption inhibitor	Postmenopausal osteoporosis	09/29/1995	P
18 Bicalutamide (Casodex)	Ani Pharms	Androgen receptor antagonist	Advanced prostate cancer	10/04/1995	S
19 Lamivudine (Epivir)	Viiv Hlthcare	HIV reverse transcriptase inhibitor	HIV-1 infection	11/17/1995	P
20 Glimepiride (Amaryl)	Sanofi	Insulin secretagogue	Type 2 diabetes	11/30/1995	S
21 Saquinavir mesylate (Invirase)	Roche	HIV protease inhibitor	HIV-1 infection	12/06/1995	P
22 Cetirizine HCl (Zyrtec allergy)	J&J	Histamine H1 receptor antagonist	Allergy symptoms	12/08/1995	S
23 Amifostine (Ethylol)	Clinigen	Binds to and detoxifies cytotoxic platinum-containing metabolites of cisplatin	Cisplatin caused cumulative renal toxicity in patients with ovarian cancer	12/08/1995	P, O
24 Riluzole (Rilutek)	Covis	Glutamate antagonist	Amyotrophic lateral sclerosis	12/12/1995	P, O
25 Cefbuten dihydrate (Cedax)	SI Pharms	Cephalosporin antibiotic, inhibits bacterial cell wall synthesis by binding to specific PBPs	Chronic bronchitis, acute bacterial otitis media, pharyngitis, and tonsillitis	12/20/1995	S
26 Ioxilan (Oxilan-300)	Guerbet	Non-ionic X-ray contrast agent	Angiography, urography, and computed tomography imaging	12/21/1995	S
27 Porfimer sodium (Photofrin)	Pinnacle Biologs	A photosensitizer used for photodynamic therapy	Advanced esophageal cancer	12/27/1995	P, O
28 Anastrozole (Arimidex)	Ani Pharms	Aromatase inhibitor	Advanced breast cancer in post-menopausal women	12/27/1995	S
29 Ibutilide fumarate (Corvert)	Pfizer	Delays repolarization by activation of a slow, inward sodium current	The rapid conversion of atrial fibrillation or atrial flutter of recent onset to sinus rhythm	12/28/1995	S

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1996 New molecular entities = 51					
1 Cefepime HCl (Maxipime)	Hospira	Bacterial cell wall synthesis inhibitor	Pneumonia caused by <i>Streptococcus pneumoniae</i>	01/18/1996	S
2 Technetium Tc-99m tetrofosmin kit (Myoview)	Janssen Pharms	Radioactive diagnostic agent	Myocardial perfusion imaging for heart disease diagnosis	03/03/1995	S
3 Ritonavir (Norvir)	AbbVie	HIV protease inhibitor	HIV-1 infection	03/01/1996	P
4 Indinavir sulfate (Crixivan)	Merck & Co	HIV protease inhibitor	HIV-1 infection	03/13/1996	P
5 Iodixanol (Visipaque 270)	GE Healthcare	Non-ionic X-ray contrast agent	Angiocardiology	03/22/1996	S
6 Trandolapril (Mavik)	AbbVie	Angiotensin-converting enzyme (ACE) inhibitor	Hypertension and left ventricular dysfunction	04/26/1996	S
7 Sodium phenylbutyrate (Buphenyl)	Horizon Therap	Pro-drug of phenylacetate, which conjugates with glutamine to form phenylacetylglutamine	Urea cycle disorders	04/30/1996	P, O
8 Docetaxel (Taxotere)	Sanofi	Microtubule-stabilizing agent	Locally advanced or metastatic breast cancer	05/14/1996	P
9 Gemcitabine HCl (Gemzar)	Eli Lilly	DNA synthesis inhibitor	Locally advanced or metastatic pancreatic cancer	05/15/1996	P
10 Topotecan HCl (Hycamtin)	Novartis	DNA topoisomerases inhibitor	Relapsed small cell lung cancer	05/28/1996	P
11 Adapalene (Differin)	Galderma Labs	Retinoid	Acne	05/31/1996	S
12 Latanoprost (Xalatan)	Upjohn	Prostaglandin F2 α receptor agonist	Open-angle glaucoma or ocular hypertension	06/05/1996	P
13 Albendazole (Albenza)	Impax Labs	Microtubule-destabilizing agent, binds to the colchicine-sensitive site of β -tubulin	Neurocysticercosis (<i>Taenia solium tapeworm</i>), Hydatid (<i>Echinococcus tapeworm</i>)	06/11/1996	P, O
14 Mirtazapine (Remeron)	Organon USA	5-HT _{2/3} receptors antagonist; α 2 adrenergic auto- and hetero-receptors antagonist	Major depression	06/14/1996	S
15 Irinotecan HCl (Camptosar)	Pfizer	Topoisomerase I inhibitor	Metastatic colorectal cancer	06/14/1996	P
16 Nevirapine (Viramune)	Boehringer Ingelheim	HIV reverse transcriptase inhibitor	HIV-1 infection	06/21/1996	P
17 Meropenem (Merrem)	Pfizer	Inhibits cell-wall synthesis by binding to PBPs	Bacterial meningitis caused by <i>Haemophilus influenzae</i> , <i>Neisseria meningitidis</i> and penicillin-susceptible isolates of <i>Streptococcus pneumoniae</i>	06/21/1996	S
18 Cidofovir (Vistide)	Gilead Sciences	Viral DNA polymerase inhibitor	Cytomegalovirus retinitis in patients with AIDS	06/26/1996	S
19 Remifentanyl HCl (Ultiva)	Mylan Institutional	μ -opioid agonist	Adjunct to an anesthetic	07/12/1996	S
20 Fexofenadine HCl (Allegra)	Chattem Sanofi	Histamine H1 receptor antagonist	Seasonal allergic rhinitis	07/25/1996	S
21 Fosphenytoin sodium (Cerebyx)	Parke Davis	Voltage-dependent neuronal sodium channels inhibitor	Epilepsy	08/05/1996	S
22 Bentoquatam (Ivy block)	Stand Homeopath	Physical shield against exposure to the irritating substance	Protects skin from the plant oils	08/26/1996	P
23 Ferumoxides (Feridex I.V.)	Amag Pharms	Superparamagnetic iron oxide, MRI contrast agent	Enhances the T2 weighted imaging for liver lesions diagnosis	08/30/1996	S
24 Midodrine HCl (Proamatine)	Takeda	α 1-adrenergic receptor agonist	Orthostatic hypotension	09/06/1996	P, O
25 Brimonidine tartrate (Alphagan)	Allergan	α 2-adrenergic receptor agonist	Open-angle glaucoma or ocular hypertension	09/06/1996	S
26 Urea C-13 (Breathtek UBT for H-pylori)	Otsuka America	¹³ C labeled urea	Initial diagnosis or post-treatment monitoring of <i>Helicobacter pylori</i> infection	09/17/1996	S
27 Nilutamide (Nilandron)	Concordia	Androgen receptor antagonist	Metastatic prostate cancer	09/19/1996	S
28 Ropivacaine HCl (Naropin)	Fresenius Kabi	Blocks the sodium-channel and decreases chances of depolarization and consequent action potentials	Local or regional anesthesia for surgery and acute pain management	09/24/1996	S
29 Penciclovir (Denavir)	Mylan	HSV DNA polymerase inhibitor	Recurrent herpes labialis	09/24/1996	S
30 Pentosan polysulfate sodium (Elmiron)	Janssen Pharms	FGF-1/2/4 antagonist	Bladder pain or discomfort caused by interstitial cystitis	09/26/1996	S, O
31 Zafirlukast (Accolate)	Strides Pharma	Leukotriene D4 and E4 receptor antagonist	Prophylaxis and chronic treatment of asthma	09/26/1996	S
32 Olanzapine (Zyprexa)	Lilly	Dopamine D2 receptor antagonist	Schizophrenia and bipolar disorder	09/30/1996	S
33 Butenafin HCl (Mentax)	Mylan	Squalene epoxidation inhibitor	Pityriasis versicolor due to <i>M. furfur</i> ; Interdigital tinea pedis, tinea corporis and tinea cruris due to <i>E. floccosum</i>	10/18/1996	S
34 Betaine (Cystadane)	Recordati Rare	Methyl group donor	Hypercytinemia	10/25/1996	P, O
35 Azelastine HCl (Astelin)	Mylan Spclt Viatris	Histamine H1-receptor antagonis	Seasonal allergic rhinitis	11/01/1996	S
36 Ivermectin (Stromectol)	Merck & Co	Glutamate-gated chloride ion channels activator	Head lice, onchocerciasis, and other worms	11/22/1996	P
37 Donepezil HCl (Aricept)	Eisai	Acetylcholinesterase inhibitor	Alzheimer's disease	11/25/1996	P
38 Tizanidine HCl (Zanaflex)	Covis	α 2-adrenergic receptor agonist	Relieves the spasms and increased muscle tone caused by multiple sclerosis	11/27/1996	S, O
39 Ferumoxsil (Gastromark)	Amag Pharms	MRI contrast agent	Enhanced MRI of bowel delineation	12/06/1996	S
40 Zileuton (Zyflo)	Chiesi	5-lipoxygenase inhibitor	Prophylaxis and chronic treatment of asthma	12/09/1996	S

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
1996 New molecular entities = 51					
41 Amlexanox (Aphthasol)	Uluru	Inhibits the slow-reacting substance of anaphylaxis release, IL-3 antagonist	Allergic asthma and rhinitis	12/17/1996	P
42 Atorvastatin calcium (Lipitor)	Upjohn	HMG CoA reductase inhibitor	Hyperlipidemia	12/17/1996	P
43 Miglitol (Glyset)	Pfizer	Membrane-bound intestinal α -glucoside hydrolase enzymes inhibitor	Type 2 diabetes	12/18/1996	S
44 Olopatadine HCl (Pataday twice daily relief)	Alcon Labs	Histamine H1 antagonist	Itching associated with allergic conjunctivitis	12/18/1996	S
45 Sparfloxacin (Zagam)	Mylan	Bacterial DNA gyrase inhibitor	Bacterial infections of the respiratory tract	12/19/1996	S
46 Fosfomycin tromethamine (Monurol)	Zambon SPA	Phosphoenolpyruvate synthetase inhibitor	Urinary tract infections (acute cystitis) caused by Escherichia coli and Enterococcus faecalis	12/19/1996	S
47 Glatiramer acetate (Copaxone)	Teva	Binds to MHC and inhibits the T cell response to several myelin antigens	Relapsing forms of multiple sclerosis	12/20/1996	S, O
48 Cabergoline (Dostinex)	Pfizer	Dopamine D2 receptor agonist	Hyperprolactinemia	12/23/1996	S
49 Valsartan (Diovan)	Novartis	Angiotensin II receptor blocker	Hypertension	12/23/1996	S
50 Danaparoid sodium (Orgaran)	Aspen Global	Factor IIa (Thrombin) and factor Xa inhibitor	Prophylaxis of post-operative deep vein thrombosis	12/24/1996	S
51 Topiramate (Topamax)	Janssen Pharms	Voltage-dependent neuronal sodium channels inhibitor, GABA-A receptor stimulator, and APMA glutamate receptors blocker	Epilepsy	12/24/1996	S
1996 Biologics license applications = 9					
1 Respiratory syncytial virus immune globulin [human] (RespiGAM)	MedImmune	Respiratory syncytial virus (RSV) immune globulin	Prevention of respiratory syncytial virus (RSV) in high risk infants	01/18/1996	N/A
2 Interferon beta-1a (Avonex)	Biogen	Recombinant human interferon β -1a	Relapsing forms of multiple sclerosis	05/17/1996	O
3 Corticorelin ovine triflutate (Acthrel)	Ferring	Synthetic human corticotropin-releasing hormone (hCRH)	Pituitary and ectopic production of ACTH in patients with ACTH-dependent Cushing's syndrome	05/23/1996	O
4 Insulin lispro recombinant (Humalog)	Eli Lilly	Recombinant human insulin	Type 1 & 2 diabetes	06/14/1996	N/A
5 Arcitumomab (CEA-Scan)	Immunomedics	^{99m}Tc labelled anti-CEA mouse IgG1 (Fab)	Recurrent colorectal cancer imaging	06/28/1996	O
6 Imciromab pentetate (Myoscint)	Centocor	^{111}In labelled anti-myosin mouse IgG2a (Fab)	Cardiac imaging	07/03/1996	N/A
7 Nofetumomab merpentan (Verluma)	Boehringer Ingelheim	^{99m}Tc labelled anti-EpCAM (and/or CD20/MS4A1) mouse IgG2b (Fab)	Small cell lung cancer imaging	8/20/1996	N/A
8 Capromab pentetide (Prostascint)	Cytogen	^{111}In labelled anti-PSMA mouse mAb	Diagnosis of metastatic prostate cancer	10/28/1996	N/A
9 Reteplase (Retavase)	EKR Therap	Recombinant plasminogen activator which catalyzes the cleavage of endogenous plasminogen to generate plasmin	Myocardial infarction, ischemic stroke, and pulmonary emboli	10/30/1996	N/A

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
1997 New molecular entities = 36					
1 Troglitazone (Rezulin)	Pfizer	PPAR γ ligand	Type 2 diabetes	01/29/1997	P
2 Imiquimod (Aldara)	Bausch	Toll-like receptor 7 agonist	External genital and perianal warts	02/27/1997	S
3 Tiludronate disodium (Skelid)	Sanofi	Protein-tyrosine-phosphatase inhibitor and osteoclastic proton pump inhibitor	Paget's disease of the bone	03/07/1997	S
4 Anagrelide HCl (Agrylin)	Takeda	Phosphodiesterase 3 (PDE3) and phospholipase A2 (PLA2) inhibitor	Thrombocythemia, secondary to myeloproliferative neoplasms	12/06/1996	S
5 Nelfinavir mesylate (Viracept)	Agouron Pharms	HIV protease inhibitor	HIV-1 infection	03/14/1997	P
6 Samarium Sm-153 lexidronam pentasodium (Quadramet)	Lantheus Medical	¹⁵³ Sm labelled Radiopharmaceutical, chelator moiety associates with hydroxyapatite crystals concentrated in areas of bone turnover	Bone metastasis of tumor induced pain	03/28/1997	S
7 Delavirdine mesylate (Rescriptor)	Viiiv Hlthcare	HIV reverse transcriptase inhibitor	HIV-1 infection	04/04/1997	P
8 Tamsulosin HCl (Flomax)	Sanofi	α -adrenoceptor blocker	Benign prostatic hyperplasia	04/15/1997	S
9 Urea, C-14 (Pytest)	Avent	¹⁴ C labelled urea	Breath test for <i>Helicobacter pylori</i>	05/09/1997	P
10 Ardeparin sodium (Normiflo)	Pharmacia & Upjohn	Low-molecular weight heparin	Prevention of deep venous thrombosis	05/23/1997	S
11 Toremifene citrate (Fareston)	Kyowa kirin	Estrogen receptor (ER) inhibitor	ER-positive metastatic breast cancer	05/29/1997	S, O
12 Tazarotene (Tazorac)	Allergan	Prodrug of retinoid	Plaque psoriasis	06/13/1997	S
13 Mibefradil 2HCl (Posicor)	Roche	Calcium channel blocker	Hypertension and chronic angina pectoris	06/20/1997	S
14 Cerivastatin sodium (Baycol)	Bayer	HMG CoA reductase inhibitor	Hyperlipidemia	06/26/1997	S
15 Pramipexole 2HCl (Mirapex)	Boehringer Ingelheim	Non-ergot dopamine agonist	Idiopathic Parkinson's disease	07/01/1997	S
16 Bromfenac sodium (Duract)	Wyeth Pharms	Cyclooxygenase-2 (COX-2) inhibitor	Acute pain following surgery	07/15/1997	S
17 Letrozole (Femara)	Novartis	Aromatase inhibitor	Advanced breast cancer	07/25/1997	S
18 Dolasetron mesylate (Anzemet)	Validus Pharms	5-HT ₃ receptor antagonist	Chemotherapy-induced nausea and vomiting	09/11/1997	S
19 Arbutamine HCl (Genesa)	Gensia automedics	α 1-adrenergic receptor agonist	Adjunctive diagnosis of coronary artery disease	09/12/1997	S
20 Ropinirole HCl (Requip)	GlaxoSmithKline	Non-ergot dopamine agonist	Parkinson's disease	09/19/1997	S
21 Fenoldopam mesylate (Corlopan)	Hospira	Dopamine D1 receptor agonist	Hypertension	09/23/1997	S
22 Quetiapine fumarate (Seroquel)	AstraZeneca	Dopamine D2 and 5-HT _{2A} receptors antagonist	Bipolar disorder, schizophrenia, and major depressive disorder	09/26/1997	S
23 Tiagabine HCl (Gabitril)	Cephalon	γ -Aminobutyric-acid (GABA) reuptake inhibitor	Epilepsy	09/30/1997	S
24 Irbesartan (Avapro)	Sanofi	Angiotensin II receptor blocker	Hypertension	09/30/1997	S
25 Grepafloxacin HCl (Raxar)	Otsuka	Bacterial topoisomerase II (DNA gyrase) and topoisomerase IV inhibitor	Mild to moderate infections caused by <i>Haemophilus influenzae</i> , <i>Streptococcus pneumoniae</i> , or <i>Moraxella catarrhalis</i>	11/06/1997	S
26 Clopidogrel bisulfate (Plavix)	Sanofi	Adenosine diphosphate inhibitor	Prevents blood clots in peripheral vascular disease, coronary artery disease, and cerebrovascular disease	11/17/1997	S
27 Sibutramine HCl (Meridia)	Abbott	Norepinephrine, serotonin and dopamine reuptake inhibitor	Obesity	11/22/1997	S
28 Zolmitriptan (Zomig)	IPR	5-HT _{1B/D/F} receptor agonist	Migraine	11/25/1997	S
29 Mangafodipir trisodium (Teslascan)	IC Targets	MRI contrast agent	Imaging of liver lesions with suspected metastatic disease or hepatocellular carcinomas	11/26/1997	S
30 Fomepizole (Antizol)	PAR Pharm	Alcohol dehydrogenase inhibitor	Antidote for ethylene glycol or methanol poisoning	12/04/1997	S, O
31 Cefdinir (Omnicef)	AbbVie	Cell wall synthesis inhibitor	Bacterial infections, including pneumonia, acute exacerbations of chronic bronchitis, acute maxillary sinusitis, pharyngitis/tonsillitis and skin infections	12/04/1997	S
32 Raloxifene HCl (Evista)	Eli Lilly	Estrogen receptor modulator	Osteoporosis in postmenopausal women	12/09/1997	P
33 Trovafloxacin mesylate (Trovan)	Pfizer	Bacterial topoisomerase II (DNA gyrase) and topoisomerase IV inhibitor	Gonorrhea and chlamydia	12/18/1997	S
34 Eprosartan mesylate (Teveten)	AbbVie	Angiotensin II receptor antagonist	Hypertension	12/22/1997	S
35 Repaglinide (Prandin)	Gemini Labs	Insulin secretagogue	Type 2 diabetes	12/22/1997	P
36 Emedastine difumarate (Emadine)	Novartis	Histamine H1-receptor antagonist	Allergic conjunctivitis	12/29/1997	S
1997 Biologics license applications = 6					
1 Autologous cultured chondrocytes (Carticel)	Genzyme Tissue Repair	Autologous cultured chondrocytes (Cell therapy)	Knee cartilage damage	08/22/1997	N/A
2 Interferon alfacon-1 (Infergen)	Amgen	Recombinant human interferon	Hepatitis C virus infection	10/06/1997	N/A
3 Oprelvekin (Neumega)	Genetics institute	Recombinant human interleukin-11 (IL-11)	Chemotherapy-induced thrombocytopenia	11/25/1997	N/A

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
1997 Biologics license applications = 6					
4 Rituximab (Rituxan)	Genentech	CD20-directed mAb	B-cell non-Hodgkin's lymphoma	11/26/1997	O
5 Daclizumab (Zenapax)	Roche	CD25 (IL-2 receptor)-directed mAb	Prophylaxis of acute organ rejection in patients receiving renal transplants	12/10/1997	N/A
6 Becaplermin (Regranex)	Smith & Nephew	Recombinant human platelet-derived growth factor (PDGF)	Ulcers caused by diabetic neuropathy	12/16/1997	N/A

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
1998 New molecular entities = 26					
1 Tolcapone (Tasmar)	Bausch	Catechol-O-methyltransferase inhibitor	Parkinson's disease	01/29/1998	S
2 Naratriptan HCl (Amerge)	GlaxoSmithKline	5-HT _{1B/D} receptors agonist	Migraine headache	02/10/1998	S
3 Loteprednol etabonate (Lotemax)	Bausch & Lomb	Corticosteroid	Steroid responsive inflammatory condition of the eye	03/09/1998	S
4 Tolterodine tartrate (Detrol)	Upjohn	Muscarinic receptor antagonist	Overactive bladder with urinary incontinence, urgency, and frequency	03/25/1998	S
5 Risedronate sodium (Actonel)	APIL	Farnesyl pyrophosphate synthase inhibitor	Osteoporosis and Paget's disease of the bone	03/27/1998	S
6 Sildenafil citrate (Viagra)	Viatris	Phosphodiesterase 5 (PDE5) inhibitor	Erectile dysfunction	03/27/1998	P
7 Brinzolamide (Azopt)	Novartis	Carbonic anhydrase II inhibitor	Elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma	04/01/1998	S
8 Paricalcitol (Zemlar)	AbbVie	Synthetic vitamin D2 analog	Secondary hyperparathyroidism associated with chronic renal failure	04/17/1998	S
9 Capecitabine (Xeloda)	Roche	Prodrug of 5-FU	Metastatic breast cancer	04/30/1998	P
10 Tirofiban HCl (Aggrastat)	Medicure	Platelet glycoprotein IIb/IIIa receptor antagonist	Acute coronary syndrome	05/14/1998	P
11 Eptifibatid (Integrilin)	Schering	Platelet glycoprotein IIb/IIIa receptor antagonist	Acute coronary syndrome	05/18/1998	P
12 Candesartan cilexetil (Atacand)	Ani Pharms	Angiotensin II receptor type 1 antagonist	Hypertension	06/04/1998	S
13 Rifapentine (Priftin)	Sanofi	DNA-dependent RNA polymerase inhibitor	Active pulmonary tuberculosis caused by <i>Mycobacterium tuberculosis</i>	06/22/1998	P, O
14 Rizatriptan benzoate (Maxalt)	Merck & Co	5-HT _{1B/D} receptor agonist	Migraine headache	06/29/1998	S
15 Thalidomide (Thalomid)	Celgene	Inhibition of TNF- α release from monocytes	Erythema nodosum leprosum	07/16/1998	P, O
16 Citalopram HBr (Celexa)	Allergan	Serotonin reuptake inhibitor	Major depression	07/17/1998	S
17 Fomivirsen sodium (Vitravene preservative free)	Novartis	Human cytomegalovirus replication inhibitor through an antisense mechanism	Cytomegalovirus retinitis in patients with AIDS	08/26/1998	P
18 Leflunomide (Arava)	Sanofi	Pyrimidine synthesis inhibitor	Rheumatoid arthritis	09/10/1998	P
19 Technetium Tc-99m apcitide (Acutect)	Cis Bio Intl	^{99m} Tc labelled radioactive diagnostic agent with platelet glycoprotein IIb/IIIa receptor binding	Imaging of acute venous thrombosis in the lower extremities in patients with signs and symptoms of acute blood clots	09/14/1998	P
20 Efavirenz (Sustiva)	Bristol-Myers Squibb	HIV reverse transcriptase inhibitor	HIV-1 infection	09/17/1998	P
21 Valrubicin (Valstar)	Endo Pharm	A semisynthetic analog of anthracycline doxorubicin	BCG-refractory CIS of urinary bladder cancer	09/25/1998	P, O
22 Sevelamer HCl (Renegel)	Genzyme	Phosphate binder	Hyperphosphatemia with chronic kidney disease	10/30/1998	S
23 Telmisartan (Micardis)	Boehringer Ingelheim	Angiotensin II receptor antagonist	Hypertension	11/10/1998	S
24 Abacavir sulfate (Ziagen)	Viiiv Hlthcare	HIV reverse transcriptase inhibitor	HIV infection	12/17/1998	P
25 Modafinil (Provigil)	Cephalon	Indirect dopamine receptor agonist	Sleep apnea, narcolepsy, or shift work disorder	12/24/1998	S, O
26 Celecoxib (Celebrex)	Upjohn	Cyclooxygenase-2 (COX-2) inhibitor	Osteoarthritis and rheumatoid arthritis	12/31/1998	P
1998 Biologics license applications = 10					
1 Lepirudin (Refludan)	Hoechst Marion Roussel	Protein-based direct thrombin inhibitor	Heparin-associated thrombocytopenia (type 2) and thromboembolic disease	03/06/1998	P, O
2 Sacrosidase (Sucraid)	QOL Medcl	Naturally-occurring gastrointestinal enzyme derived from baker's yeast (<i>Saccharomyces cerevisiae</i>)	Congenital sucrase-isomaltase deficiency	04/09/1998	O
3 Basiliximab (Simulect)	Novartis	CD25 (IL-2R α)-directed mAb	Acute rejection of renal transplant	05/12/1998	P, O
4 Palivizumab (Synagis)	Medimmune	Anti-F protein (Respiratory syncytial virus) mAb	Respiratory syncytial virus infection	06/19/1998	P
5 Calfactant (Infasurf preservative free)	ONY	Modified natural bovine pulmonary surfactant	Respiratory distress syndrome in premature infants	07/01/1998	O
6 Infliximab (Remicade)	Centocor	Anti-TNF- α mAb	Rheumatoid arthritis, Crohn's disease, and ankylosing spondylitis	08/24/1998	O
7 Trastuzumab (Herceptin)	Genentech	HER2-directed mAb	HER2-positive breast cancer	09/25/1998	P
8 Etanercept (Enbrel)	ImmuneX	Dimeric fusion protein consisting of extracellular ligand-binding portion of TNFR linked to the Fc portion of human IgG1	Rheumatoid arthritis	11/02/1998	P
9 Thyrotropin alfa (Thyrogen)	Genzyme	Recombinant human thyroid stimulating hormone	Diagnostic testing for thyroid tissue remnants following radioiodine ablation, and alongside radioactive agents to destroy thyroid tissue	11/30/1998	O
10 Anti-thymocyte globulin [Rabbit] (Thymoglobulin)	Genzyme	Purified rabbit anti-thymocyte antibody	Acute rejection of renal transplant	12/30/1998	S

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
1999 New molecular entities = 32					
1 Cilostazol (Pletal)	Otsuka	Phosphodiesterase 3 (PDE3) inhibitor	Intermittent claudication	01/15/1999	S
2 Alitretinoin (Panretin)	Concordia	9-cis-retinoic acid, a form of vitamin A	AIDS-related Kaposi's sarcoma	02/02/1999	P, O
3 Amprenavir (Agenerase)	GlaxoSmithKline	HIV-1 protease inhibitor	HIV infections	04/15/1999	N/A
4 Orlistat (Xenical)	Cheplapharm	Gastrointestinal lipase inhibitor	Obesity	04/23/1999	P
5 Rofecoxib (Vioxx)	Merck & Co	Cyclooxygenase-2 (COX-2) inhibitor	Osteoarthritis, rheumatoid arthritis, and acute pain	05/20/1999	P
6 Rosiglitazone maleate (Avandia)	Woodward	PPARs agonist	Type 2 diabetes	05/25/1999	P
7 Doxercalciferol (Hectorol)	Sanofi	Synthetic vitamin D2 analog	Secondary hyperparathyroidism in patients with chronic kidney disease	06/09/1999	S
8 Pioglitazone HCl (Actos)	Takeda	PPAR γ agonist	Type 2 diabetes	07/15/1999	P
9 Zanamivir (Relenza)	GlaxoSmithKline	Neuraminidase inhibitor	Influenza A and B virus infections	07/26/1999	P
10 Ganirelix acetate (Antagon)	Organon	GnRH antagonist	Inhibition of premature luteinizing hormone (LH) surges in women undergoing controlled ovarian hyperstimulation	05/18/1998	P
11 Technetium Tc-99m depreotide (Neo tect kit)	Cis Bio Intl	^{99m} Tc labelled radioactive diagnostic agent	Imaging of malignant lung tumors in patients with highly suspect for malignancy	08/03/1999	P
12 Temozolomide (Temodar)	Merck & Co	DNA alkylating agent	Glioblastoma	08/11/1999	P, O
13 Zaleplon (Sonata)	Pfizer	Benzodiazepine receptor agonist	Insomnia	08/13/1999	S
14 Rapacuronium bromide (Raplon)	Organon	Muscarinic acetylcholine receptor M2 antagonist	Adjunctively in anesthesia for endotracheal intubation or to facilitate mechanical ventilation	08/18/1999	S
15 Rabeprazole sodium (Aciphex)	Woodward	Proton pump inhibitor	Gastroesophageal reflux disease	08/19/1999	S
16 Sirolimus (Rapamune)	Merck & Co	Mammalian target of rapamycin (mTOR) inhibitor	Prophylaxis of organ rejection	09/15/1999	P, O
17 Epirubicin HCl (Ellence)	Pfizer	DNA topoisomerase II inhibitor	Primary breast cancer with axillary node tumor involvement	09/15/1999	P, O
18 Quinupristin; Dalfopristin (Synercid)	King Pharms	Inhibitor of early and late phase of protein synthesis in the bacterial ribosome	Vancomycin-resistant <i>Enterococcus faecium</i> (VREF) bacteremia	09/21/1999	P
19 Pemirolast potassium (Alamast)	Santen	Mast cell stabilizer, Histamine H1-receptor antagonist	Itching of the eye due to allergic conjunctivitis	09/24/1999	P
20 Dofetilide (Tikosyn)	Pfizer	Blockade of the cardiac ion channel carrying the rapid component of the delayed rectifier potassium current	Maintenance of normal sinus rhythm	10/01/1999	S
21 Entacapone (Comtan)	Orion Pharma	Catechol-O-methyl transferase inhibitor	Parkinson's disease	10/19/1999	S
22 Exemestane (Aromasin)	Pfizer	Aromatase inhibitor	ER-positive early breast cancer	10/21/1999	S, O
23 Oseltamivir Phosphate (Tamiflu)	Roche	Influenza virus neuraminidase inhibitor	Influenza A and B infections	10/27/1999	P
24 Levetiracetam (Keppra)	UCB Inc	Synaptic vesicle protein 2A (SV2A) stimulator	Epilepsy	11/30/1999	S
25 Aminolevulinic acid HCl (Levulan)	DUSA	Porphyrin precursor	Actinic keratoses	12/03/1999	S
26 Gadoversetamide (Optimark)	Liebel-Flarsheim	Gadolinium-based MRI contrast agent	MRI tests of the brain, spine, and liver	12/08/1999	S
27 Mequinol; Tretinoin (Solage)	Almirall	Substrate of tyrosinase and acts as a competitive inhibitor of the formation of melanin precursors; All-trans retinoic acid	Solar lentigines	12/10/1999	S
28 Moxifloxacin HCl (Avelox)	Bayer	Topoisomerase II (DNA gyrase) and IV inhibitor	Sinusitis, pneumonia, and secondary infections in chronic bronchitis	12/10/1999	S
29 Dexmedetomidine HCl (Precedex)	Hospira	α 2-adrenergic agonist	Sedation	12/17/1999	S, O
30 Gatifloxacin (Tequin)	Bristol-Myers Squibb	Topoisomerase II (DNA gyrase) and IV inhibitor	Bronchitis, sinusitis, pneumonia, and skin infections caused by <i>S. pneumoniae</i> , <i>H. influenzae</i> , <i>S. aureus</i> , <i>M. pneumoniae</i> , <i>C. pneumoniae</i> , <i>L. pneumophila</i> , and <i>S. pyogenes</i>	12/17/1999	N/A
31 Nitric oxide (Inomax)	Mallinckrodt Hosp	Guanylate cyclase activator	Hypoxic respiratory failure in premature neonates	12/23/1999	P, O
32 Bexarotene (Targretin)	Valeant Luxembourg	Retinoid, ligand of retinoid X receptors (RXRs)	Cutaneous T-cell lymphoma	12/29/1999	P, O
1999 Biologics license applications = 2					
1 Denileukin diftitox (Ontak)	Eisai	Fusion protein consisting of diphtheria toxin fragments and interleukin-2	Cutaneous T-cell lymphoma	02/05/1999	O
2 Poractant alfa (Curosurf)	Chiesi USA	Natural porcine lung surfactant	Respiratory distress syndrome in premature infants	11/18/1999	O

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2000 New molecular entities = 24					
1 Cevimeline HCl (Evoxac)	Daiichi Sankyo	Cholinergic agonist	Sjogren's syndrome	01/11/2000	S
2 Oxcarbazepine (Trileptal)	Novartis	Voltage-gated sodium channels inhibitor	Epilepsy	01/14/2000	S
3 Pantoprazole sodium (Protonix)	Wyeth Pharms	Proton pump inhibitor	Erosive esophagitis associated with gastroesophageal reflux disease	02/02/2000	S
4 Alosetron HCl (Lotronex)	Sebela Ireland	5-HT ₃ antagonist	Severe diarrhea-predominant irritable bowel syndrome (IBS) in women	02/09/2000	P
5 Perfluoropolyethylisopropyl ether; Polytetrafluoroethylene (Skin exposure reduction paste against chemical warfare agents)	US Army	Skin exposure reduction paste against chemical warfare agents	Contact dermatitis, friction-induced blisters, calluses and foot ulceration	02/17/2000	P
6 Zonisamide (Zonegran)	Concordia	Sodium and voltage sensitive calcium channels inhibitor	Epilepsy	03/27/2000	S
7 Articaine HCl; Epinephrine bitartrate (Septocaine)	Deproco	Articaine is a sodium channels blocker; Epinephrine is vasoconstrictor to slow absorption into the general circulation and prolong maintenance of an active tissue concentration	Local, infiltrative, or conductive anesthesia	04/03/2000	S
8 Verteporfin (Visudyne)	Valeant Luxembourg	Generation of highly reactive, short-lived singlet oxygen and reactive oxygen radicals by light in the presence of oxygen	Pathological myopia, ocular histoplasmosis, and choroidal neovascularization in macular degeneration	04/12/2000	P
9 Meloxicam (Mobic)	Boehringer Ingelheim	COX-2 inhibitor	Osteoarthritis and rheumatoid arthritis	04/13/2000	S, O
10 Linezolid (Zyvox)	Pfizer	Binds to bacterial 23S ribosomal RNA of the 50S subunit and prevents the formation of 70S initiation complex	Skin infections caused by <i>Staphylococcus aureus</i> , <i>Streptococcus pyogenes</i> , or <i>Streptococcus agalactiae</i>	04/18/2000	P
11 Rivastigmine tartrate (Exelon)	Novartis	Cholinesterase inhibitor	Mild-to-moderate Alzheimer's disease	04/21/2000	S
12 Colesevelam HCl (Welchol)	Daiichi Sankyo	Bile acid sequestrant	Hypercholesterolemia	05/26/2000	S
13 Triptorelin pamoate (Trelstar)	Verity	GnRH agonist	Advanced prostate cancer	06/15/2000	S
14 Argatroban	Novartis	Synthetic direct thrombin inhibitor derived from L-arginine	Thrombosis caused by heparin-induced thrombocytopenia	06/30/2000	S
15 Tinzaparin sodium (Innohep)	Leo Pharma	Low molecular weight heparin	Acute symptomatic deep vein thrombosis with or without pulmonary embolism	08/19/1999	S
16 Balsalazide disodium (Colazal)	Valeant Pharms	Mechanism of action of is unknown	Mild-to-moderate ulcerative colitis	07/18/2000	S
17 Docosanol (Abreva)	GlaxoSmithKline	Inhibiting fusion between the human cell plasma membrane and the herpes simplex virus (HSV) envelope	Oral-facial herpes simplex episodes	07/25/2000	S
18 Unoprostone isopropyl (Rescula)	Sucampo Pharma	Prostaglandin analog	Open-angle glaucoma or ocular hypertension	08/03/2000	P
19 Cetrorelix (Cetrotide)	Emd Serono	GnRH antagonist	Inhibition of premature LH surges in women undergoing controlled ovarian stimulation	08/11/2000	S
20 Lopinavir; Ritonavir (Kaletra)	Abbvie	HIV protease inhibitors	HIV-1 infection	09/15/2000	P
21 Arsenic trioxide (Trisenox)	Cephalon	Degradation of PML-RAR α fusion protein	Acute promyelocytic leukemia characterized by the presence of the t (15; 17) translocation or PML/RAR α gene expression	09/25/2000	P, O
22 Mifepristone (Mifeprex)	Danco Labs	Synthetic steroid, progestational and glucocorticoid hormone antagonist	Cushing's syndrome	09/28/2000	P
23 Bivalirudin (Angiomax)	Sandoz	Synthetic direct thrombin inhibitor	Heparin-induced thrombocytopenia and for the prevention of thrombosis	12/15/2000	S
24 Nateglinide (Starlix)	Novartis	Insulin secretagogue	Insulin independent diabetes	12/22/2000	S
2000 Biologics license applications = 6					
1 Insulin glargine recombinant (Lantus)	Sanofi	Recombinant human insulin [Gly (A21), Arg (B31, B32)]	Type 1 & 2 diabetes	04/20/2000	N/A
2 Gemtuzumab ozogamicin (Mylotarg)	Wyeth Pharms	CD33-directed antibody-drug conjugate (ADC)	Relapsed or refractory CD33-positive acute myeloid leukemia (AML)	05/17/2000	O
3 Tenecteplase (Tnkase)	Genentech	Recombinant human tissue plasminogen activator	Emergency treatment of myocardial infarction and pulmonary emboli	06/02/2000	N/A
4 Insulin aspart recombinant (Novolog)	Novo Nordisk	Recombinant human insulin [Asp (B28)]	Type 1 & 2 diabetes	06/07/2000	N/A
5 Choriogonadotropin alfa (Ovidrel)	Emd Serono	Recombinant human chorionic gonadotropin	Female infertility	09/20/2000	N/A
6 Botulinum toxin type B (Myobloc)	Elan Pharm	Purified botulinum toxin type B	Cervical dystonia	12/08/2000	O

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2001 New molecular entities = 23					
1 Caspofungin acetate (Cancidas)	Merck & Co	1,3-β glucan synthase inhibitor	<i>Aspergillus</i> and <i>Candida</i> infection	01/26/2001	P
2 Ziprasidone HCl (Geodon)	Viartis	5-HT _{1D/2A} receptor and dopamine D ₂ receptor antagonist, 5-HT _{1A} receptor agonist	Schizophrenia	02/05/2001	S
3 Formoterol fumarate (Foradil)	Novartis	β ₂ -adrenergic receptor agonist	Asthma and chronic obstructive pulmonary disease (COPD)	02/16/2001	S
4 Galantamine HBr (Razadyne)	Janssen Pharms	Acetylcholinesterase inhibitor	Alzheimer's disease	02/28/2001	S
5 Travoprost (Travatan)	Alcon Pharms	Synthetic prostaglandin F _{2α} analogt	Open angle glaucoma or ocular hypertension	03/16/2001	P
6 Bimatoprost (Lumigan)	Allergan	Synthetic prostaglandin analog	Open angle glaucoma or ocular hypertension	03/16/2001	P
7 Almotriptan malate (Axert)	Janssen Pharms	5-HT _{1B/D} receptor agonist	Acute migraine headaches	05/07/2001	S
8 Imatinib mesylate (Gleevec)	Novartis	Tyrosine kinase inhibitor	Chronic myeloid leukemia	05/10/2001	P
9 Drospirenone; Ethinyl estradiol (Yasmin)	Bayer	Synthetic progestin and estrogen	Contraception	05/11/2001	S
10 Perflutren (Definity)	Lantheus Medcl	Ultrasound contrast agent	Ultrasound contrast imaging in cardiology and radiology	07/31/2001	S
11 Zoledronic acid (Zometa)	Novartis	Bone-resorption inhibitor	Hypercalcemia of malignancy	08/20/2001	P, O
12 Cefditoren pivoxil (Spectracef)	Vansen Pharma	Inhibition of cell wall synthesis	Chronic bronchitis, pneumonia, pharyngitis/tonsillitis, and skin infections	08/29/2001	S
13 Ethinyl estradiol; Etonogestrel (Nuvaring)	Organon	Synthetic estrogen; Synthetic derived progestin	Contraception	10/03/2001	S
14 Tenofovir disoproxil fumarate (Viread)	Gilead Sciences	HIV-1 and HBV reverse transcriptase inhibitor	HIV-1 and HBV infection	10/26/2001	P
15 Frovatriptan succinate (Frova)	Endo Pharms	5-HT _{1B/1D} receptor agonist	Migraine headaches	11/08/2001	S
16 Valdecoxib (Bextra)	GD Searle	Cyclooxygenase-2 (COX-2) inhibitor	Osteoarthritis and dysmenorrhea	11/16/2001	S
17 Ethinyl estradiol; Norelgestromin (Ortho evra)	Janssen Pharms	Synthetic estrogen and progestin	Contraception	11/20/2001	S
18 Bosentan (Tracleer)	Actelion	Endothelin receptor antagonist	Pulmonary arterial hypertension	11/20/2001	S, O
19 Dutasteride (Avodart)	Woodward	5α-reductase inhibitor	Benign prostatic hyperplasia	11/20/2001	S
20 Ertapenem sodium (Invanz)	Merck & Co	Inhibition of cell wall synthesis	Urinary tract infection	11/21/2001	S
21 Fondaparinux sodium (Arixtra)	Mylan Ireland	Antithrombin III activator	Deep vein thrombosis (DVT)	12/07/2001	P
22 Pimecrolimus (Elidel)	Bausch	Calcineurin inhibitor	Mild to moderate atopic dermatitis	12/13/2001	S
23 Desloratadine (Clarinet)	Organon	Histamine H ₁ receptor antagonist	Allergic rhinitis and chronic idiopathic urticaria	12/21/2001	S
2001 Biologics license applications = 5					
1 Peginterferon alfa-2B (Pegintron)	Schering	Purified human interferon	HCV infection	01/19/2001	O
2 Alemtuzumab (Campath)	Genzyme	CD52-directed mAb	B-cell chronic lymphocytic leukemia	05/07/2001	O
3 Nesiritide recombinant (Natrecor)	Scios	Recombinant human B-type natriuretic peptide	Acutely decompensated congestive heart failure	08/10/2001	S
4 Darbepoetin alfa (Aranesp)	Amgen	Recombinant human erythropoietin	Anemia	09/17/2001	N/A
5 Anakinra (Kineret)	Biovitrum	Recombinant human interleukin-1 receptor antagonist	Rheumatoid arthritis and neonatal-onset multisystem inflammatory disease	11/14/2001	O

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2002 New molecular entities = 17					
1 Nitisinone (Orfadin)	Swedish Orphan	4-hydroxyphenyl-pyruvate dioxygenase inhibitor, involved in tyrosine catabolism	Hereditary tyrosinaemia type 1	01/18/2002	P, O
2 Olmesartan medoxomil (Benicar)	Daiichi Sankyo	Angiotensin II type 1 receptor antagonist	Hypertension	04/25/2002	S
3 Fulvestrant (Faslodex)	AstraZeneca	Estrogen receptor antagonist	HR-positive metastatic breast cancer	04/25/2002	S
4 Treprostinil sodium (Remodulin)	United Therap	Prostacyclin analog, vasodilator and platelet-aggregation inhibitor	Pulmonary arterial hypertension	05/21/2002	P, O
5 Voriconazole (Vfend)	Merck & Co	Triazole, inhibitor of cytochrome P450-mediated 14 α -lanosterol demethylation	Invasive aspergillosis and serious fungal infections caused by <i>Scedosporium apiospermum</i> and <i>Fusarium spp</i>	05/24/2002	S
6 Dimyristoyl lecithin; Perflhexane (Imagent)	Vesselon SPV	<i>n</i> -perfluorohexane (perflhexane) and non-animal semi-synthetic phospholipid (DMPC), increases ultrasound reflectivity of blood	Patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border	05/31/2002	S
7 Sodium oxybate (Xyrem)	Jazz	γ -hydroxybutyrate, central nervous system depressant	Narcolepsy with episodes of cataplexy	07/17/2002	P, O
8 Tegaserod maleate (Zelnorm)	Alfasigma	5-HT ₄ receptor agonist	Irritable bowel syndrome	07/24/2002	P
9 Oxaliplatin (Eloxatin)	Sanofi	Organoplatinum alkylating agent, increases tumor response rate to chemotherapy	Colorectal cancer (in combination with 5-fluorouracil and leucovorin)	08/09/2002	P
10 Adefovir dipivoxil (Hepsera)	Gilead Sciences	Acyclic nucleoside phosphonate, inhibitor of hepatitis B virus DNA polymerase	Chronic hepatitis B	09/20/2002	P
11 Eplerenone (Inspra)	Upjohn	Selective aldosterone receptor antagonist	Hypertension	09/27/2002	N/A
12 Ezetimibe (Zetia)	Organon	Inhibits intestinal cholesterol absorption, NPC1L1 blocker	Primary hyperlipidemia and familial cholesterolemia	10/25/2002	S
13 Aripiprazole (Abilify)	Otsuka	Serotonin and dopamine receptors agonist	Schizophrenia	11/15/2002	S, O
14 Nitazoxanide (Alinia)	Romark	Antiprotozoal agent	Paediatric diarrhoea caused by <i>Cryptosporidium spp.</i> and <i>Giardia spp.</i>	11/22/2002	P, O
15 Atomoxetine HCl (Strattera)	Eli Lilly	Selective noradrenaline-reuptake inhibitor	Attention-deficit hyperactivity disorder	11/26/2002	S
16 Icodextrin (Extraneal)	Baxter Hlthcare	Isosmotic peritoneal dialysis solution containing glucose polymers	Continuous ambulatory peritoneal dialysis of diabetic patients, automated peritoneal dialysis for the management of end-stage renal disease	12/20/2002	S, O
17 Eletriptan HCl (Relpax)	Upjohn	Selective 5-HT _{1B/D} receptor agonist	Migraine	12/26/2002	S
2002 Biologics license applications = 4					
1 Pegfilgrastim (Neulasta)	Amgen	PEGylated form of recombinant human granulocyte colony-stimulating factor (G-CSF)	Febrile neutropenia or myelosuppressive chemotherapy-induced neutropenia	01/31/2002	N/A
2 Ibritumomab tiuxetan (Zevalin)	IDEC Pharms	¹¹¹ In and ⁹⁰ Y labelled CD20-specific radiotherapeutic mAb	B-cell non-Hodgkin's lymphoma	02/19/2002	O
3 Peginterferon alfa-2A (Pegasys)	Roche	Recombinant human interferon	Hepatitis B and C virus infection	10/16/2002	N/A
4 Adalimumab (Humira)	AbbVie	TNF α -directed mAb	Rheumatoid arthritis, Crohn's disease, and ankylosing spondylitis	12/31/2002	O

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2003 New molecular entities = 20					
1 Enfuvirtide (Fuzeon)	Roche	HIV-1 gp41 fusion inhibitor	HIV-1 infection	03/13/2003	P
2 Aprepitant (Emend)	Merck & Co	NK1 receptor antagonist	Chemotherapy-induced nausea	03/26/2003	P
3 Gemifloxacin mesylate (Factive)	LG Chem	Bacterial topoisomerase II (DNA gyrase) and topoisomerase IV inhibitor	Bacterial infections, including <i>S. pneumoniae</i> , <i>H. influenzae</i> , <i>H. parainfluenzae</i> , or <i>M. catarrhalis</i> , <i>S. pneumoniae</i> , et al.	04/04/2003	S
4 Gefitinib (Iressa)	AstraZeneca	EGFR kinase inhibitor	Non-small-cell lung cancer	05/05/2003	P
5 Bortezomib (Velcade)	Takeda Pharms	Proteasome inhibitor	Multiple myeloma	05/13/2003	P, O
6 Ibandronate sodium (Boniva)	Roche	Bisphosphonate	Osteoporosis	05/16/2003	S
7 Alfuzosin HCl (Uroxatral)	Concordia	α 1-adrenoceptor antagonist	Benign prostate hyperplasia	06/12/2003	S
8 Atazanavir sulfate (Reyataz)	Bristol-Myers Squibb	HIV protease inhibitor	HIV-1 infection	06/20/2003	P
9 Emtricitabine (Emtriva)	Gilead Sciences	HIV reverse transcriptase inhibitor	HIV-1 infection	07/02/2003	S
10 Palonosetron HCl (Aloxi)	Helsinn	5-HT ₃ receptor antagonist	Chemotherapy-induced nausea	07/25/2003	S
11 Miglustat (Zavesca)	Actelion	Glucosylceramide synthase inhibitor	Gaucher's disease	07/31/2003	S, O
12 Rosuvastatin calcium (Crestor)	IPR	HMG CoA reductase inhibitor	Hypercholesterolemia	08/12/2003	S
13 Vardenafil HCl (Levitra)	Bayer	Phosphodiesterase 5 (PDE5) inhibitor	Erectile dysfunction	08/19/2003	S
14 Daptomycin (Cubicin)	Cubist Pharms	Cyclic lipopeptide, cell membrane/wall constituent biosynthesis inhibitor	Skin infections, or bloodstream infections caused by <i>Staphylococcus aureus</i>	09/12/2003	P
15 Ferric hexacyanoferrate II (Radiogardase [Prussian blue])	Heyl Chemisch	Metal-binding complex	Systemic contamination with radioactive cesium and/or radioactive or non-radioactive thallium	10/02/2003	P, O
16 Memantine HCl (Namenda)	Allergan	NMDA receptor antagonist	Alzheimer's disease	10/16/2003	S
17 Epinastine HCl (Elestat)	Allergan	Histamine H1-receptor antagonist	Hay fever	10/16/2003	S
18 Tadalafil (Cialis)	Lilly	Phosphodiesterase 5 (PDE5) inhibitor	Erectile dysfunction	11/21/2003	S
19 Abarelix (Plenaxis)	Speciality European	GnRH receptor antagonist	Advanced prostate cancer	11/25/2003	P
20 Sertaconazole nitrate (Ertaczo)	Bausch	Imidazole-derivative antifungal	Tinea pedis	12/10/2003	S
2003 Biologics license applications = 8					
1 Alefacept (Amevive)	Biogen	CD2-directed mAb	Psoriasis	01/31/2003	N/A
2 Pegvisomant (Somavert)	Pharmacia	Growth hormone receptor antagonist	Acromegaly	03/25/2003	O
3 Desirudin recombinant (Iprivask)	Bausch	Direct human thrombin inhibitor	Prophylaxis of deep vein thrombosis for patients undergoing hip replacement surgery	04/04/2003	N/A
4 Agalsidase beta (Fabrazyme)	Genzyme	Recombinant human α -galactosidase A	Fabry disease	04/24/2003	O
5 Laronidase (Aldurazyme)	Biomarin	Recombinant α -L-iduronidase	Mucopolysaccharidosis type 1	04/30/2003	O
6 Omalizumab (Xolair)	Genentech	IgE-directed mAb	Asthma	06/20/2003	N/A
7 Tositumomab and iodine I-131 tositumomab (Bexxar)	Corixa	CD20-directed radiotherapeutic mAb	Non-Hodgkin's lymphoma	06/30/2003	P, O
8 Efalizumab (Raptiva)	Genentech	CD11a-directed mAb	Psoriasis	10/27/2003	N/A

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2004 New molecular entities = 28					
1 Tiotropium bromide (Spiriva)	Boehringer Ingelheim	Muscarinic M1/5 receptors antagonist	Chronic obstructive pulmonary disease (COPD)	01/30/2004	S
2 Pemetrexed disodium (Alimta)	Eli Lilly	Folate analog	Malignant pleural mesothelioma	02/04/2004	P, O
3 Cinacalcet HCl (Sensipar)	Amgen	Calcimimetic, calcium sensing receptor agonist	Secondary hyper-parathyroidism, hypercalcaemia	03/08/2004	P, O
4 Telithromycin (Ketek)	Sanofi	Ketolide antibiotic	Respiratory infections	04/01/2004	S
5 Secretin synthetic human (Chirostim)	ChiRhoClin	Pancreatic and gastrin secretagogue	Exocrine pancreas dysfunction, gastrinoma (diagnostic)	04/09/2004	P
6 Apomorphine HCl (Apokyn)	MDD US	Non-ergoline dopamine D2 agonist	Parkinson's disease	04/20/2004	P, O
7 Tinidazole (Tindamax)	Mission Pharma	Antiprotozoal agent	Giardiasis, amoebiasis and trichomoniasis	05/17/2004	S, O
8 Azacitidine (Vidaza)	Celgene	Antineoplastic pyrimidine nucleoside analogue, DNA methyltransferase inhibitor	Myelodysplastic syndrome	05/19/2004	P, O
9 Rifaximin (Xifaxan)	Salix Pharmas	Rifaximin-based non-systemic antibiotic	Traveler's diarrhea	05/25/2004	S, O
10 Trospium chloride (Sanctura)	Allergan	Antimuscarinic antispasmodic	Overactive bladder	05/28/2004	S
11 L-Glutamine (NutreStore)	Emmaus Medcl	Amino acid supplement	Short bowel syndrome	06/10/2004	S, O
12 Acamprosate calcium (Campral)	Forest Labs	Neurotransmitter γ -aminobutyric acid (GABA) analog	Alcohol dependence	07/29/2004	P
13 Duloxetine HCl (Cymbalta)	Lilly	Serotonin- and norepinephrine-reuptake inhibitor	Diabetic peripheral neuropathy	08/03/2004	S
14 Pentetate calcium trisodium	Hameln	Chelating agent	Internal radioactive contamination	08/11/2004	P, O
15 Pentetate zinc trisodium	Hameln	Chelating agent	Internal radioactive contamination	08/11/2004	P, O
16 Pegaptanib sodium (Macugen)	Valeant Pharms	Selective VEGF antagonist	Neovascular age-related macular degeneration	09/17/2004	P
17 Lanthanum carbonate (Fosrenol)	Takeda	Phosphate binder	Hyperphosphatemia in end-stage renal failure	10/26/2004	S
18 ω 3-acid ethyl esters (Lovaza)	Woodward	Lipid-regulating agent	Hypertriglyceridemia	11/10/2004	S
19 Erlotinib HCl (Tarceva)	OSI Pharmas	EGFR inhibitor	Non-small-cell lung cancer (NSCLC)	11/18/2004	P
20 Solifenacin succinate (Vesicare)	Astellas	Muscarinic M2/3 receptors antagonist	Overactive bladder	11/19/2004	S
21 Gadobenate dimeglumine (Multihance)	Bracco	Gadolinium-based MRI contrast agent	MRI imaging of liver, heart and central nervous system (CNS)	11/23/2004	S
22 Eszopiclone (Lunesta)	Sunovion Pharms	Non-benzodiazepine hypnotic, GABA-A receptor stimulator	Insomnia	12/15/2004	S
23 Trypan blue (Visionblue)	DORC	Selective staining of the anterior lens capsule	Cataract surgery	12/16/2004	P
24 Darifenacin HBr (Enablex)	APIL	Selective muscarinic M3 receptor antagonist	Overactive bladder	12/22/2004	S
25 Ziconotide acetate (Prialt)	Tersera	N-type calcium channel blocker	Severe chronic pain	12/28/2004	P
26 Clotfarabine (Clolar)	Genzyme	Nucleoside antimetabolite, DNA synthesis inhibitor	Relapsed or refractory acute lymphoblastic leukemia	12/28/2004	P, O
27 Iloprost (Ventavis)	Actelion	Prostacyclin analog	Pulmonary arterial hypertension	12/29/2004	P, O
28 Pregabalin (Lyrica)	Upjohn	Neurotransmitter γ -aminobutyric acid (GABA) analog	Diabetic peripheral neuropathy and post-herpetic neuralgia pain	12/30/2004	P
2004 Biologics license applications = 8					
1 Cetuximab (Erbix)	ImClone	EGFR-directed mAb	Colorectal cancer	02/12/2004	N/A
2 Bevacizumab (Avastin)	Genentech	VEGF-A-directed mAb	Colorectal cancer	02/26/2004	O
3 Insulin glulisine recombinant (Apidra)	Sanofi	Recombinant human insulin [Lys (B3), Glu (B29)]	Type 1 and type 2 diabetes	04/16/2004	N/A
4 Hyaluronidase (Vitrase)	Bausch & Lomb	Connective-tissue-permeability modifier (Ovine)	Adjunct in subcutaneous urography for improving resorption of radiopaque agents	05/05/2004	N/A
5 Hyaluronidase (Amphadase)	Amphastar Pharm	Connective-tissue-permeability modifier (Bovine)		10/26/2004	N/A
6 Technetium (99m Tc) fanolesomab (NeutroSpec)	Palatin Technologies	^{99m} Tc labelled CD15-directed mAb	Imaging and detection of appendicitis	07/02/2004	N/A
7 Natalizumab (Tysabri)	Biogen Idec	α 4-integrin-directed mAb	Crohn's disease or multiple sclerosis	11/23/2004	N/A
8 Palifermin (Kepivance)	Biovitrum	Recombinant human keratinocyte growth factor	Oral mucositis following radiation or chemotherapy	12/15/2004	N/A

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2005 New molecular entities = 13					
1 Pramlintide acetate (Symlin)	AstraZeneca	Amylin analog, glucoregulatory hormone	Type 1 and 2 diabetes	03/16/2005	S
2 Micafungin sodium (Mycamine)	Astellas	Inhibits fungal cell wall by inhibiting β -1,3-D-glucan synthesis	Candida infections in patients undergoing hematopoietic stem cell transplantation	03/16/2005	S
3 Entecavir (Baraclude)	Bristol-Myers Squibb	Nucleoside analog	Chronic hepatitis B virus infection	03/29/2005	P
4 Exenatide synthetic (Byetta)	AstraZeneca	Incretin mimetics, human glucagon-like peptide-1 (GLP-1) receptor agonist	Type 2 diabetes	04/28/2005	S
5 Tigecycline (Tygacil)	Merck & Co	Tetracycline antibiotic, inhibits protein translation in bacteria by binding to the 30S ribosomal subunit	Complicated skin and skin structure infections and complicated intra-abdominal infections	06/15/2005	P
6 Tipranavir (Aptivus)	Boehringer Ingelheim	HIV-1 protease inhibitor	HIV-1 infection	06/22/2005	P
7 Ramelteon (Rozerem)	Takeda	Melatonin receptor agonist	Insomnia	07/22/2005	S
8 Nepafenac (Nevanac)	Novartis	Nonsteroidal anti-inflammatory prodrug	Pain and inflammation associated with cataract surgery	08/19/2005	P
9 Nelarabine (Arranon)	Novartis	Purine nucleoside analog, inhibits the DNA elongation	T-cell acute lymphoblastic leukaemia and T-cell lymphoblastic lymphoma	10/28/2005	P, O
10 Deferasirox (Exjade)	Novartis	Iron chelator	Chronic iron overload due to blood transfusions	11/02/2005	P, O
11 Sorafenib tosylate (Nexavar)	Bayer	Multi-target TKI (VEGFR2/3, PDGFR β , FLT3, KIT, RAF1, and BRAF)	Advanced renal cell carcinoma	12/01/2005	P, O
12 Lenalidomide (Revlimid)	Celgene	Thalidomide derivative, immunomodulatory and antiangiogenic agent	Transfusion-dependent anemia due to myelodysplastic syndromes associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities	12/27/2005	P, O
13 Conivaptan HCl (Vaprisol)	Cumberland Pharms	Antidiuretic hormone (Vasopressin) inhibitor	Euvolemic hyponatremia in hospitalized patients	12/29/2005	S
2005 Biologics license applications = 7					
1 Galsulfase (Naglazyme)	Biomarin	Recombinant human N-acetylgalactosamine 4-sulfatase	Mucopolysaccharidosis VI	05/31/2005	P, O
2 Insulin detemir recombinant (Levemir)	Novo Nordisk	Recombinant human insulin [Δ Thr (B30)]	Type 1 and 2 diabetes	06/16/2005	N/A
3 Mecasermin recombinant (Increlex)	Ipsen	Recombinant DNA-origin human insulin-like growth factor 1 (IGF-1)	Growth failure in pediatric patients with primary IGF-1 deficiency or growth hormone gene deletion	08/30/2005	P, O
4 Hyaluronidase (Hydase)	Akorn	Connective-tissue-permeability modifier (Bovine)	Hypodermoclysis, and in subcutaneous urography for improving resorption of radiopaque agents	10/25/2005	P
5 Hyaluronidase recombinant human (Hyalenex recombinant)	Halozyme Therap	Connective-tissue-permeability modifier (Human)	Subcutaneous urography for improving resorption of radiopaque agents	12/02/2005	P
6 Mecasermin rinfabate recombinant (iPlex)	Insmed	Recombinant DNA-origin IGF-1	Growth failure in children with severe primary IGF-1 deficiency	12/12/2005	O
7 Abatacept (Orencia)	Bristol-Myers Squibb	Selective T-cell co-stimulation modulator	Rheumatoid arthritis	12/23/2005	P

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2006 New molecular entities = 18					
1 Sunitinib malate (Sutent)	CPPI CV	Multi-target TKI (VEGFRs, PDGFR α/β , CSF1R, KIT, and FLT3)	Imatinib-resistant gastrointestinal stromal tumor and advanced renal cell carcinoma	01/26/2006	P
2 Ranolazine (Ranexa)	Gilead Sciences	Sodium and potassium ion channel inhibitor	Chronic angina	01/27/2006	S
3 Lubiprostone (Amitiza)	Sucampo Pharma	Chloride channel inhibitor	Constipation	01/31/2006	S
4 Anidulafungin (Eraxis)	Vicuron Holdings	Fungal cell-wall synthesis inhibitor	Esophageal candidiasis	02/17/2006	S
5 Decitabine (Dacogen)	Otsuka	Demethylating agent	Myelodysplastic syndrome	05/02/2006	S, O
6 Varenicline tartrate (Chantix)	Merck & Co	Nicotinic acetylcholine receptor (nACh-R) agonist	Smoking cessation	05/10/2006	P
7 Rasagiline mesylate (Azilect)	Teva	Monoamine oxidase B inhibitor	Parkinson's disease	05/16/2006	S
8 Darunavir (Prezista)	Janssen Prods	HIV-1 protease inhibitor	HIV-1 infection	06/23/2006	P
9 Dasatinib (Sprycel)	Bristol-Myers Squibb	Tyrosine kinase inhibitor	Chronic myeloid leukemia	06/28/2006	P, O
10 Avobenzone; Ecamsule; Octocrylene (Anthelios SX)	Loreal USA	UVA/UVB filter	Prevention of sunburn	07/21/2006	S
11 Posaconazole (Noxafil)	Schering	Fungal cell-wall synthesis inhibitor	<i>Aspergillus</i> and <i>Candida</i> infection	09/15/2006	P
12 Bismuth subcitrate potassium; Metronidazole; Tetracycline HCl (Pylera)	Allergan	Bismuth subcitrate potassium inhibits peptic activity; Metronidazole inhibits bacterial and protozoal nucleic acid synthesis; Tetracycline HCl interferes with protein synthesis by preventing binding of tRNA to the mRNA-ribosome complex	Gastric and duodenal ulcers caused by <i>H. pylori</i> infection	09/28/2006	S
13 Vorinostat (Zolinza)	Merck & Co	Histone deacetylase inhibitor	Cutaneous T-cell lymphoma	10/06/2006	P, O
14 Sitagliptin phosphate (Januvia)	Merck & Co	DPP4 inhibitor	Type 2 diabetes	10/16/2006	S
15 Ciclesonide (Omnaris)	Covis	Corticosteroid	Allergic rhinitis	10/20/2006	S
16 Telbivudine (Tyzeka)	Novartis	Reverse transcriptase inhibitor	Chronic hepatitis B	10/25/2006	S
17 Sinecatechins (Veregen)	Ani Pharms	Antioxidant	External genital and perianal warts	10/31/2006	S
18 Paliperidone (Invega)	Janssen Pharms	Dopamine D2 and 5-HT _{2A} receptor antagonist	Schizophrenia	12/19/2006	S
2006 Biologics license applications = 4					
1 Alglucosidase alfa (Myozyme)	Genzyme	Recombinant human α -glucosidase	α -glucosidase deficiency (Pompe disease)	04/28/2006	O
2 Ranibizumab (Lucentis)	Genentech	VEGF-A-directed mAb fragment	Neovascular (wet) age-related macular degeneration	06/30/2006	N/A
3 Idursulfase (Elaprase)	Shire	Recombinant human iduronate-2-sulfatase	Hunter syndrome (Mucopolysaccharidosis II)	07/24/2006	O
4 Panitumumab (Vectibix)	Amgen	EGFR-directed mAb	EGFR-expressing metastatic colorectal carcinoma	09/27/2006	N/A

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2007 New molecular entities = 17					
1 Lisdexamfetamine dimesylate (Vyvanse)	Takeda	Prodrug of dextroamphetamine with CNS stimulant activity	Attention-deficit/hyperactivity disorder	02/23/2007	S
2 Aliskiren Hemifumarate (Tekturna)	Noden Pharma	Direct renin inhibitor	Hypertension	03/05/2007	S
3 Lapatinib Ditosylate (Tykerb)	Novartis	HER2 and EGFR inhibitor	Advanced or metastatic breast cancer (HER2-positive)	03/13/2007	P
4 Retapamulin (Altabax)	Almirall	Bacterial protein-synthesis inhibitor	Impetigo	04/12/2007	S
5 Rotigotine (Neupro)	UCB Inc	Dopamine receptor agonist	Early-stage idiopathic Parkinson's disease	05/09/2007	S
6 Temsirolimus (Torisel)	Merck & Co	Mammalian target of rapamycin (mTOR) inhibitor	Advanced renal cell carcinoma	05/30/2007	P, O
7 Ambrisentan (Letairis)	Gilead Sciences	Endothelin receptor antagonist	Pulmonary arterial hypertension	06/15/2007	P, O
8 Maraviroc (Selzentry)	Viiv Hlthcare	CCR5 co-receptor antagonist	CCR5-tropic HIV-1	08/06/2007	P
9 Ammonia N-13 (Ammonia N 13)	Feinstein	¹³ N labelled radioactive diagnostic agent	Radioactive agent for positron emission tomography diagnosis of coronary artery disease	08/23/2007	S
10 Lanreotide (Somatuline depot)	Ipsen Pharma	Somatostatin analog	Acromegaly	08/30/2007	S, O
11 Doripenem (Doribax)	Shionogi	Synthetic broad-spectrum carbapenem antibiotic	Urinary tract infections	10/12/2007	S
12 Raltegravir potassium (Isentress)	Merck & Co	HIV integrase strand transfer inhibitor	HIV-1 infection	10/12/2007	P
13 Ixabepilone (Ixempra)	R-Pharm US	Microtubule-stabilizing agent	Advanced or metastatic breast cancer	10/16/2007	P
14 Nilotinib HCl (Tasigna)	Novartis	BCR-ABL kinase inhibitor	Chronic myelogenous leukemia	10/29/2007	S, O
15 Sapropterin 2HCl (Kuvan)	Biomarin Pharm	Synthetic tetrahydrobiopterin, co-factor for the enzyme phenylalanine hydroxylase	Hyperphenylalaninemia	12/13/2007	P, O
16 Nebivolol HCl (Bystolic)	Allergan	β-adrenoceptor antagonist	Hypertension	12/17/2007	S
17 Hydroxyethyl starch (Voluven)	Fresenius Kabi	Blood volume expander	Serious blood volume loss	12/27/2007	N/A
2007 Biologics license applications = 2					
1 Eculizumab (Soliris)	Alexion Pharm	Complement protein C5-directed mAb	Paroxysmal nocturnal hemoglobinuria	03/16/2007	P, O
2 Methoxy polyethylene glycol-epoetin beta (Mircera)	Roche	Erythropoietin receptor activator	Anemia associated with chronic renal failure	11/14/2007	P

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2008 New molecular entities = 22					
1 Etravirine (Intencele)	Janssen R&D	Non-nucleoside HIV-1 reverse transcriptase inhibitor	HIV-1 infection	01/18/2008	P
2 Fosaprepitant dimeglumine (Emend)	Merck & Co	Prodrug of aprepitant, NK1 receptor antagonist	Nausea and vomiting caused by chemotherapy	01/25/2008	S
3 Desvenlafaxine Succinate (Pristiq)	Pfizer	Selective serotonin and noradrenaline reuptake inhibitor	Major depressive disorder	02/29/2008	S
4 Bendamustine HCl (Treanda)	Cephalon	Mechlorethamine derivative with DNA-alkylating activity	Chronic lymphocytic leukemia	03/20/2008	P, O
5 Regadenoson (lexiscan)	Astellas	A _{2A} adenosine receptor agonist	Pharmacological stress agent for radionuclide imaging	04/10/2008	S
6 Methylnaltrexone bromide (Relistor)	Salix Pharms	Peripherally acting μ opioid receptor antagonist	Opioid-induced constipation	04/24/2008	S
7 Alvimopan (Entereg)	Cubist Pharms	Peripherally acting μ opioid receptor antagonist	To accelerate gastrointestinal recovery following bowel resection surgery	05/20/2008	S
8 Difluprednate (Durezol)	Novartis	Ocular corticosteroid thought to act by the induction of phospholipase A2 inhibitory proteins	Inflammation and pain associated with ocular surgery	06/23/2008	P, O
9 Gadoxetate disodium (Eovist)	Bayer	Gadolinium-based contrast agent	MRI diagnosis of liver lesions	07/03/2008	S
10 Clevidipine (Cleviprex)	Chiesi	Short-acting dihydropyridine calcium channel antagonist	Peri-operative hypertension when oral therapy is not feasible or not desirable	08/01/2008	S
11 Tetrabenazine (Xenazine)	Bausch	Monoamine-depleting agent	Chorea associated with Huntington's disease	08/15/2008	P, O
12 Iobenguane sulfate I-123 (AdreView)	GE Healthcare	Taken up by the noradrenaline transporter in adrenergic nerve terminals	Radiopharmaceutical agent, detection of primary or metastatic pheochromocytoma or neuroblastoma	09/19/2008	P, O
13 Silodosin (Rapaflo)	Allergan	α 1-adrenoceptor antagonist	Benign prostatic hyperplasia	10/08/2008	S
14 Lacosamide (Vimpat)	UCB Inc	Selectively enhances slow inactivation of voltage-gated sodium channels and binds to collapsin response mediator protein 2	Partial-onset seizures in epilepsy	10/28/2008	S
15 Fesoterodine fumarate (Toviaz)	Pfizer	Competitive muscarinic receptor antagonist	Overactive bladder disorder	10/31/2008	S
16 Rufinamide (Banzel)	Eisai	Sodium channel activity modulator	Seizures associated with Lennox-Gastaut syndrome	11/14/2008	S
17 Eltrombopag olamine (Promacta)	Novartis	Thrombopoietin receptor agonist	Thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura	11/20/2008	P, O
18 Tapentadol HCl (Nucynta)	Collegium Pharm	μ opioid receptor agonist and noradrenaline reuptake inhibitor	Moderate to severe acute pain	11/20/2008	S
19 Fospropofol disodium (lusedra)	Eisai	Prodrug of propofol	Monitored anesthesia care sedation	12/12/2008	S
20 Plerixafor (Mozobil)	Genzyme	CXCR4 antagonist	Autologous transplantation in patients with non-Hodgkin's lymphoma and multiple myeloma	12/15/2008	P, O
21 Gadofosveset Trisodium (Vasovist)	Lantheus Medcl	Gadolinium-based contrast agent	Magnetic resonance angiography (MRA) diagnosis of aortoiliac occlusive disease (AIOD)	12/22/2008	S
22 Degarelix acetate (Firmagon)	Ferring	GnRH receptor antagonist	Advanced prostate cancer	12/24/2008	S
2008 Biologics license applications = 5					
1 Somatropin (Accretropin)	Emergent	Recombinant human growth hormone	Growth failure, growth hormone deficiency	01/23/2008	N/A
2 Rilonacept (Arcalyst)	Kiniksa Pharma (UK) Ltd	IL-1 blocker, dimeric fusion protein consisting of portions of IL-1R and the IL-1R accessory protein linked to the Fc portion IgG1	Cryopyrin-associated periodic syndromes including familial cold autoinflammatory syndrome and Muckle-wells syndrome	02/27/2008	P, O
3 Certolizumab pegol (Cimzia)	UCB Inc	TNF α blocker, pegylated anti-TNF α IgG1 (Fab)	Crohn's disease	04/22/2008	S
4 Romiplostim (Nplate)	Amgen	Thrombopoietin receptor agonist, thrombopoiesis stimulating dimer Fc-peptide fusion protein (Peptibody)	Thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura	08/22/2008	P, O
5 Insulin aspart protamine recombinant; Insulin aspart recombinant (Novolog mix 50/50)	Novo Nordisk	Recombinant human insulin [Asp (B28)]	Type 1 & 2 diabetes	08/26/2008	N/A

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2009 New molecular entities = 20					
1 Milnacipran HCl (Savella)	Allergan	Selective serotonin and noradrenaline reuptake inhibitor	Fibromyalgia	01/14/2009	S
2 Febuxostat (Uloric)	Takeda	Xanthine oxidase inhibitor	Hyperuricemia in patients with gout	02/13/2009	S
3 Everolimus (Afinitor)	Novartis	Mammalian target of rapamycin (mTOR) inhibitor	Advanced renal cell carcinoma	03/30/2009	P
4 Artemether; Lumefantrine (Coartem)	Novartis	Works against the erythrocytic stages of <i>P. falciparum</i> by inhibiting nucleic acid and protein synthesis	Malaria	04/07/2009	P, O
5 Benzyl alcohol (Ulesfia)	Shionogi	Closes the respiratory spiracles of lice and causes the lice to asphyxiate	Head lice	04/09/2009	S
6 Iloperidone (Fanapt)	Vanda Pharms	Atypical antipsychotic agent, 5-HT _{2A} and dopamine D ₂ receptors antagonist	Schizophrenia	05/06/2009	S
7 Tolvaptan (Samsca)	Otsuka	Selective vasopressin V ₂ receptor antagonist	Hypervolemic and euvolemic hyponatremia, including patients with heart failure, cirrhosis and syndrome of inappropriate antidiuretic hormone	05/19/2009	S
8 Besifloxacin HCl (Besivance)	Bausch & Lomb	Fluoroquinolone antimicrobial agent that inhibits bacterial topoisomerase II (DNA gyrase) and topoisomerase IV	Bacterial conjunctivitis	05/28/2009	S
9 Dronedarone HCl (Multaq)	Sanofi	Multi-channel blocker, including potassium, sodium, and calcium channels	Atrial fibrillation and atrial flutter	07/01/2009	P
10 Prasugrel HCl (Effient)	Daiichi Sankyo	Platelet P _{2Y12} purinoceptor inhibitor	Reduction of thrombotic cardiovascular events in patients with acute coronary syndrome undergoing percutaneous coronary intervention	07/10/2009	P
11 Saxagliptin HCl (Onglyza)	AstraZeneca	Dipeptidyl peptidase 4 inhibitor	Type 2 diabetes	07/31/2009	S
12 Pitavastatin calcium (Livalo)	Kowa Co	HMG CoA reductase inhibitor	Hyperlipidemia and mixed dyslipidemia	08/03/2009	S
13 Asenapine Maleate (Saphris)	Allergan	Atypical antipsychotic agent, 5-HT _{2A} and dopamine D ₂ receptors antagonist	Schizophrenia and bipolar disorder	08/13/2009	S
14 Vigabatrin (Sabril)	Lundbeck	Irreversible γ-aminobutyric acid transaminase inhibitor	Infantile spasms in children aged 1 month to 2 years and complex partial seizures in adults	08/21/2009	P, O, S
15 Bepotastine besilate (Bepreve)	Bausch & Lomb	Histamine H ₁ receptor antagonist	Allergic conjunctivitis	09/04/2009	S
16 Telavancin HCl (Vibativ)	Cumberland Pharms	Semi-synthetic derivative of vancomycin, bacterial cell wall synthesis inhibitor	Complicated skin and skin structure infections	09/11/2009	S
17 Pralatrexate (Folotyn)	Acrotech	Folate analogue metabolic inhibitor that competitively inhibits dihydrofolate reductase	Peripheral T cell lymphoma	09/24/2009	P, O
18 Pazopanib HCl (Votrient)	Novartis	Multi-target TKI (VEGFRs, PDGFRα/β, FGFR1/2, KIT)	Advanced renal cell carcinoma	10/19/2009	S
19 Romidepsin (Istodax)	Celgene	Histone deacetylase inhibitor	Cutaneous T cell lymphoma	11/05/2009	S
20 Capsaicin (Qutenza)	Averitas	Transient receptor potential vanilloid 1 (TRPV1) receptor agonist	Neuropathic pain associated with post-herpetic neuralgia	11/16/2009	S, O
2009 Biologics license applications = 6					
1 Golimumab (Simponi)	Centocor Ortho Biotech	TNFα-directed mAb	Rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis	04/24/2009	S
2 Abobotulinum-toxin A (Dysport)	Ipsen Biopharm	Acetylcholine release inhibitor and neuromuscular blocking agent	Cervical dystonia and glabellar lines	04/29/2009	S
3 Canakinumab (Ilaris)	Novartis	Interleukin-1β-directed mAb	Cryopyrin-associated periodic syndromes	06/17/2009	P, O
4 Ustekinumab (Stelara)	Centocor Ortho Biotech	Interleukin (IL)-12 and IL-23 (p40 subunit)-directed mAb	Moderate-to-severe plaque psoriasis	09/25/2009	S
5 Ofatumumab (Arzerra)	Novartis	CD20-directed mAb	Chronic lymphocytic leukemia	10/26/2009	P, O
Ofatumumab (Kesimpta)			Relapsing forms of multiple sclerosis		
6 Ecallantide (Kalbitor)	Dyax Corp	Plasma kallikrein inhibitor	Hereditary angioedema	12/01/2009	P, O

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2010 New molecular entities = 14					
1 Dalfampridine (Ampyra)	Acorda Therapeutics	Potassium channel blocker	Improving walking in patients with multiple sclerosis	01/22/2010	P, O
2 Liraglutide recombinant (Victoza)	Novo Nordisk	Glucagon-like peptide 1 (GLP1) receptor agonist	Type 2 diabetes	01/25/2010	P
3 Carglumic acid (Carbaglu)	Orphan Europe	Carbamoyl phosphate synthetase 1 (CPS1) activator	Acute hyperammonemia	03/18/2010	P, O
4 Polidocanol (Asclera)	Chemisch Fbrk Krsslr	Sclerosing agent	Uncomplicated spider veins and uncomplicated reticular veins	03/30/2010	S
5 Dienogest; Estradiol valerate (Natazia)	Bayer	Semisynthetic progestogen; Estrogen	Contraception	05/06/2010	S
6 Cabazitaxel (Jevtana kit)	Sanofi	Microtubule-stabilizing agent	Prostate cancer	06/17/2010	P
7 Alcaftadine (Lastacaft)	Allergan	Histamine H1 receptor antagonist	Allergic conjunctivitis	07/28/2010	S
8 Ulipristal acetate (Ella)	Lab HRA Pharma	Progesterone receptor modulator	Contraception	08/13/2010	S
9 Fingolimod HCl (Gilenya)	Novartis	Sphingosine 1-phosphate (S1P) receptor modulator	Multiple sclerosis	09/21/2010	P
10 Dabigatran etexilate mesylate (Pradaxa)	Boehringer Ingelheim	Direct thrombin inhibitor	Stroke prevention in atrial fibrillation	10/19/2010	P
11 Lurasidone HCl (Latuda)	Sunovion Pharms	Atypical antipsychotic agent, 5-HT _{2A/7} and dopamine D ₂ receptors antagonist	Schizophrenia	10/28/2010	S
12 Ceftaroline fosamil (Teflaro)	Cerexa	Broad-spectrum cephalosporin antibiotic	Skin and skin-structure infections; Community acquired pneumonia	10/29/2010	S
13 Tesamorelin acetate (Egrifta)	Theratechnologies	Growth hormone-releasing factor analog	HIV lipodystrophy	11/10/2010	S
14 Eribulin mesylate (Halaven)	Eisai	Microtubule-destabilizing agent	Breast cancer	11/15/2010	P
2010 Biologics license applications = 7					
1 Tocilizumab (Actemra)	Genentech	Interleukin-6 (IL-6) receptor-directed mAb	Rheumatoid arthritis	01/08/2010	N/A
2 Collagenase clostridium histolyticum (Xiaflex)	Auxilium Pharms	Purified collagenase clostridium histolyticum	Dupuytren's contracture	02/02/2010	O
3 Velaglucerase alfa (Vpriv)	Shire	Recombinant human β -glucocerebrosidase	Gaucher's disease	02/26/2010	P
4 Alglucosidase alfa (Lumizyme)	Genzyme	Recombinant human acid α -glucosidase	Pompe's disease	05/24/2010	O
5 Denosumab (Prolia)	Amgen	RANK ligand (RANKL)-directed mAb	Postmenopausal osteoporosis	06/01/2010	O
6 IncobotulinumtoxinA (Xeomin)	Merz Pharms	Acetylcholine release inhibitor and neuromuscular blocking agent	Cervical dystonia and blepharospasm	07/30/2010	N/A
7 Pegloticase (Krystexxa)	Horizon Pharma	PEGylated uric acid specific enzyme	Gout	09/14/2010	O

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2011 New molecular entities = 24					
1 Ioflupane I-123 (Datiscan)	GE Healthcare	Dopamine transporter-binding imaging agent	Parkinsonian syndromes (Imaging agent)	01/14/2011	P
2 Spinosad (Natroba)	ParaPro	Causes neuronal hyperexcitation in insects	Head lice	01/18/2011	S
3 Vilazodone HCl (Viibryd)	Allergan	Selective serotonin reuptake inhibitor and 5-HT _{1A} partial agonist	Major depressive disorder	01/21/2011	S
4 Azilsartan kamedoxomil (Edarbi)	Arbor Pharms	Angiotensin II type 1 receptor antagonist	Hypertension	02/25/2011	S
5 Roflumilast (Daliresp)	Forest Laboratories	Phosphodiesterase 4 (PDE4) inhibitor	COPD exacerbations	02/28/2011	S
6 Gadobutrol (Gadavist)	Bayer	Gadolinium-based contrast agent	Blood-brain barrier imaging	03/14/2011	S
7 Gabapentin enacarbil (Horizant)	Arbor Pharms	Voltage-activated calcium channel inhibitor	Moderate-to-severe restless legs syndrome	04/06/2011	S
8 Vandetanib (Caprelsa)	Genzyme	Multi-target TKI (VEGFR2/3, EGFR, and RET)	Unresectable or metastatic medullary thyroid cancer	04/06/2011	P, O
9 Abiraterone acetate (Zytiga)	Janssen Biotech	CYP17A1 inhibitor	Metastatic castration-resistant prostate cancer	04/28/2011	P
10 Linagliptin (Tradjenta)	Boehringer Ingelheim	Dipeptidyl peptidase 4 inhibitor	Type 2 diabetes	05/02/2011	S
11 Boceprevir (Victrelis)	Merck & Co	NS3/4A protease inhibitor	HCV genotype 1	05/13/2011	P
12 Rilpivirine HCl (Edurant)	Janssen Prods	Non-nucleoside HIV reverse transcriptase inhibitor	HIV-1 infection	05/20/2011	S
13 Telaprevir (Incivek)	Vertex Pharms	NS3/4A protease inhibitor	HCV genotype 1	05/23/2011	P
14 Fidaxomicin (Dificid)	Cubist Pharms	RNA polymerase inhibitor	<i>Clostridium difficile</i> -associated diarrhea	05/27/2011	P
15 Ezogabine (Potiga)	GlaxoSmithKline	Potassium channel opener	Partial-onset seizures	06/10/2011	S
16 Indacaterol maleate (Arcapta neohaler)	Novartis	Long-acting β_2 -adrenergic receptor agonist	Chronic obstructive pulmonary disease (COPD)	07/01/2011	S
17 Rivaroxaban (Xarelto)	Janssen Pharms	Factor Xa inhibitor	Prophylaxis of deep vein thrombosis in hip and knee replacement surgery	07/01/2011	S
18 Ticagrelor (Brilinta)	AstraZeneca	P2Y ₁₂ platelet inhibitor	Thrombotic cardiovascular events in patients with acute coronary syndrome	07/20/2011	S
19 Vemurafenib (Zelboraf)	Roche	BRAF inhibitor	BRAF-positive unresectable or metastatic melanoma	08/17/2011	P, O
20 Icatibant acetate (Firazyr)	Shire	Bradykinin B2 receptor antagonist	Hereditary angioedema	08/25/2011	P, O
21 Crizotinib (Xalkori)	Merck & Co	Multi-target TKI (ALK, ROS1, and MET)	ALK-positive advanced or metastatic NSCLC	08/26/2011	P, O
22 Deferiprone (Ferroprox)	Chiesi	Iron chelator	Transfusional iron overload due to thalassemia syndromes	10/14/2011	S, O
23 Clobazam (Onfi)	Lundbeck	Benzodiazepine, partial GABA-A receptors agonist	Seizures associated with Lennox-Gastaut syndrome	10/21/2011	S, O
24 Ruxolitinib phosphate (Jakafi)	Incyte Corp	JAK1/JAK2 inhibitor	Intermediate or high-risk myelofibrosis	11/16/2011	P, O
2011 Biologics license applications = 6					
1 Belimumab (Benlysta)	Human Genome Sciences	B-lymphocyte stimulator (BLyS)-directed mAb	Active, autoantibody-positive, systemic lupus erythematosus	03/09/2011	P
2 Ipilimumab (Yervoy)	Bristol-Myers Squibb	Cytotoxic T-lymphocyte antigen 4 (CTLA-4)-directed mAb	Unresectable or metastatic melanoma	03/25/2011	P, O
3 Belatacept (Nulojix)	Bristol-Myers Squibb	T cell co-stimulation blocker; soluble fusion protein consisting of extracellular domain of human CTLA-4 and modified Fc region of IgG	Organ rejection in kidney transplant	06/15/2011	S, O
4 Brentuximab vedotin (Adcetris)	Seattle Genetics	CD30-directed antibody drug conjugate (ADC)	Hodgkin's lymphoma; systemic anaplastic large cell lymphoma	08/19/2011	P, O
5 Aflibercept (Eylea)	Regeneron Pharmaceuticals	VEGF inhibitor; recombinant protein consisting of binding domains of VEGFR and Fc region of IgG	Neovascular (wet) age-related macular degeneration	11/18/2011	P
6 Asparaginase <i>Erwinia chrysanthemi</i> (Erwinaze)	EUSA Pharma (USA)	<i>Erwinia chrysanthemi</i> -derived L-asparaginase	Acute lymphoblastic leukemia	11/18/2011	P, O

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2012 New molecular entities = 32					
1 Ingenol mebutate (Picato)	Leo Labs	MOA unknown	Actinic keratosis	01/23/2012	S
2 Axitinib (Inlyta)	Pfizer	VEGFRs inhibitor	Advanced renal cell carcinoma	01/27/2012	S
3 Vismodegib (Erivedge)	Genentech	Smoothened (Hedgehog pathway) inhibitor	Metastatic or locally advanced basal cell carcinoma	01/30/2012	P
4 Ivacaftor (Kalydeco)	Vertex Pharms	CFTR potentiator	Cystic fibrosis in patients with the G551D mutation in the <i>CFTR</i> gene	01/31/2012	P, O
5 Tafluprost (Zioptan)	Akorn	Selective prostaglandin F prostanoid receptor agonist	Elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	02/10/2012	S
6 Lucinactant (Surfaxin)	Windtree Therap	Synthetic peptide-containing surfactant that mimics human surfactant protein-B	Prevention of respiratory distress syndrome	03/06/2012	S
7 Peginesatide acetate (Omontys)	Takeda	Synthetic, pegylated erythropoiesis stimulating agent	Anemia due to chronic kidney disease	03/27/2012	S
8 Florbetapir F-18 (Amyvid)	Avid Radiopharms	¹⁸ F labelled radioactive diagnostic agent	Diagnostic agent to estimate amyloid-β plaques in patients with suspected Alzheimer's disease	04/06/2012	S
9 Avanafil (Stendra)	Metuchen Pharms	Phosphodiesterase 5 (PDE5) inhibitor	Erectile dysfunction	04/27/2012	S
10 Lorcaserin (Belviq)	Eisai	5-HT _{2C} receptor agonist	Obesity	06/27/2012	S
11 Mirabegron (Myrbetriq)	APGDI	β ₃ -adrenergic receptor agonist	Overactive bladder	06/28/2012	S
12 Citric acid; Magnesium oxide; Sodium picosulfate (Prepopik)	Ferring Pharms	Osmotic and stimulant laxatives	Cleansing of the colon before colonoscopy	07/16/2012	S
13 Carfilzomib (Kyprolis)	Onyx Therap	20S proteasome inhibitor	Multiple myeloma	07/20/2012	S, O
14 Acclidinium bromide (Tudorza pressair)	AstraZeneca	Long-acting antimuscarinic agent	Bronchospasms associated with COPD	07/23/2012	S
15 Cobicistat; Elvitegravir; Emtricitabine; Tenofovir disoproxil fumarate (Stribild)	Gilead Sciences	Cytochrome P450 inhibitor; HIV-1 integrase inhibitor; NRTI; Acyclic nucleoside phosphonate analog	HIV-1 infection	08/27/2012	S
16 Linaclotide (Linzess)	Allergan	Guanylyl cyclase C agonist	Irritable bowel syndrome with constipation; Chronic idiopathic constipation	08/31/2012	S
17 Enzalutamide (Xtandi)	Astellas	Androgen receptor inhibitor	Metastatic castration-resistant prostate cancer	08/31/2012	P
18 Bosutinib monohydrate (Bosulif)	Pfizer	BCR-ABL inhibitor; SRC family kinase inhibitor	Chronic, accelerated or blast phase Ph ⁺ chronic myelogenous leukemia	09/04/2012	S, O
19 Teriflunomide (Aubagio)	Sanofi	Dihydroorotate dehydrogenase inhibitor	Relapsing forms of multiple sclerosis	09/12/2012	S
20 Choline C-11	MCPRF	¹¹ C labelled choline analog, radioactive diagnostic agent	Diagnostic agent for imaging of patients with suspected prostate cancer recurrence	09/12/2012	P
21 Regorafenib (Stivarga)	Bayer	Multi-target TKI (RET, VEGFRs, KIT, PDGFRα/β, FGFR1/2, RAF1, BRAFWT, and BRAFV ^{600E})	Metastatic colorectal cancer	09/27/2012	P
22 Perampanel (Fycompa)	Eisai	Non-competitive ionotropic AMPA glutamate receptor antagonist	Partial-onset seizures in patients with epilepsy	10/22/2012	S
23 Omacetaxine mepesuccinate (Synribo)	Teva	Cephalotaxine, inhibits protein chain elongation by binding the large ribosomal subunit	Chronic or accelerated-phase chronic myeloid leukemia	10/26/2012	S, O
24 Tofacitinib citrate (Xeljanz)	Pfizer	JAK inhibitor	Severely active rheumatoid arthritis	11/06/2012	S
25 Cabozantinib S-malate (Cometriq)	Exelixis	Multi-target TKI (VEGFRs, MET, RET, FLT3, KIT, TIE2, and AXL)	Progressive, metastatic medullary thyroid cancer	11/29/2012	P, O
26 Pasireotide diaspertate (Signifor)	Recordati Rare	Somatostatin analog	Cushing's disease	12/14/2012	P, O
27 Ponatinib HCl (Iclusig)	Takeda	Multi-kinase inhibitor (BCR-ABL, KIT, RET and FLT3)	Chronic, accelerated or blast-phase chronic myeloid leukemia	12/14/2012	P, O
28 Teduglutide recombinant (Gattex kit)	NPS Pharms	Glucagon-like peptide-2 (GLP-2) analog	Short bowel syndrome	12/21/2012	S, O
29 Lomitapide mesylate (Juxtapid)	Amryt	Microsomal triglyceride transfer protein inhibitor	Homozygous familial hypercholesterolemia	12/21/2012	S, O
30 Apixaban (Eliquis)	Bristol-Myers Squibb	Factor Xa inhibitor	Stroke and systemic embolism in patients with non-valvular atrial fibrillation	12/28/2012	P
31 Bedaquiline fumarate (Sirturo)	Janssen Therap	Diarylquinoline antimycobacterial	Pulmonary multidrug-resistant tuberculosis	12/28/2012	P, O
32 Crofelemer (Mytesi)	Napo Pharms	CFTR and CaCC channels inhibitor	HIV-associated diarrhea	12/31/2012	P
2012 Biologics license applications = 7					
1 Glucarpidase (Voraxaze)	BTG International	Recombinant carboxypeptidase G2	Toxic plasma methotrexate concentrations in patients with delayed methotrexate clearance	01/17/2012	P, O
2 Taliglucerase alfa (Elelyso)	Pfizer	Recombinant human lysosomal enzyme β-glucocerebrosidase, produced in carrot cells	Gaucher's disease	05/01/2012	S, O
3 Pertuzumab (Perjeta)	Genentech	HER2-directed mAb	HER2-positive metastatic breast cancer	06/08/2012	P
4 Ziv-aflibercept (Zaltrap)	Sanofi	Soluble receptor decoy that binds VEGF-A, VEGF-B, and PlGF	Metastatic colorectal cancer	08/03/2012	P

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2012 Biologics license applications = 7					
5 Tbo-Filgrastim (Neutroval)	Sicor Biotech	Methionyl human G-CSF	Severe neutropaenia in patients with non-myeloid malignancies	08/29/2012	S
6 Ocriplasmin (Jetrea)	Thrombogenics	Recombinant truncated form of human plasmin	Symptomatic vitreomacular adhesion	10/17/2012	P
7 Raxibacumab	Human Genome Sciences	Human mAb against <i>Bacillus anthracis</i> toxin	Anthrax	12/14/2012	P, O

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2013 New molecular entities = 25					
1 Alogliptin benzoate (Nesina)	Takeda	DPP4 inhibitor	Type 2 diabetes	01/25/2013	S
2 Mipomersen sodium (Kynamro)	Kastle Theraps	Oligonucleotide inhibitor of apolipoprotein B100 synthesis	Homozygous familial hypercholesterolemia	01/29/2013	S, O
3 Pomalidomide (Pomalyst)	Celgene	Thalidomide analog, immunomodulatory antineoplastic agent	Multiple myeloma	02/08/2013	S, O
4 Ospemifene (Osphena)	Duchesnay	Estrogen receptor modulator	Moderate to severe dyspareunia due to menopause	02/26/2013	S
5 Technetium TC 99m tilmanocept (Lymphoseek kit)	Cardinal Health 414	^{99m} Tc labelled radioactive diagnostic agent	Lymphatic mapping in patients with breast cancer or melanoma	03/13/2013	S
6 Gadoterate meglumine (Dotarem)	Guerbet	Gadolinium-based contrast agent	Contrast agent to visualize disruption of the blood-brain barrier	03/20/2013	P
7 Dimethyl fumarate (Tecfidera)	Biogen	MOA unknown; activates NRF2 pathway	Relapsing forms of multiple sclerosis	03/27/2013	S
8 Canagliflozin (Invokana)	Janssen Pharms	Sodium-dependent glucose cotransporter 2 (SGLT2) inhibitor	Type 2 diabetes	03/29/2013	S
9 Fluticasone furoate; Vilanterol trifenate (Breo ellipta)	GlaxoSmithKline	Corticosteroid plus long-acting β 2-adrenergic agonist	Chronic obstructive pulmonary disease	05/10/2013	S
10 Radium Ra-223 dichloride (Xofigo)	Bayer	α -particle-emitting radioactive therapeutic	Castration-resistant prostate cancer	05/15/2013	P
11 Dabrafenib mesylate (Tafinlar)	Novartis	Kinase inhibitor with activity against BRAF ^{V600E/D/K} , wild-type BRAF and other kinases	Unresectable or metastatic melanoma with BRAF ^{V600E} mutation	05/29/2013	S, O
12 Trametinib dimethyl sulfoxide (Mekinist)	Novartis	MEK1 and MEK2 kinase inhibitor	Unresectable or metastatic melanoma with BRAF ^{V600E} mutation	05/29/2013	S, O
13 Afatinib dimaleate (Gilotrif)	Boehringer Ingelheim	EGFR, HER2, and HER4 inhibitor	Metastatic NSCLC with EGFR exon 19 deletions or exon 21 (L858R) substitution mutations	07/12/2013	P, O
14 Dolutegravir sodium (Tivicay)	Viiv Hlthcare	HIV-1 integrase strand transfer inhibitor	HIV-1 infection in adults and children, in combination with other antiretroviral agents	08/12/2013	P
15 Vortioxetine HBr (Brintellix)	Takeda	Serotonin reuptake inhibitor	Major depressive disorder	09/30/2013	S
16 Bazedoxifene acetate; Estrogens, conjugated (Duavee)	Wyeth Pharms	Conjugated estrogens with an estrogen receptor modulator	Moderate to severe vasomotor symptoms associated with menopause and prevention of postmenopausal osteoporosis	10/03/2013	S
17 Riociguat (Adempas)	Bayer	Soluble guanylyl cyclase stimulator	Persistent or recurrent chronic thromboembolic pulmonary hypertension and pulmonary arterial hypertension	10/08/2013	P, O
18 Macitentan (Opsumit)	Actelion	Endothelin receptor antagonist	Pulmonary arterial hypertension	10/18/2013	S, O
19 Flutemetamol F-18 (Vizamyl)	GE Healthcare	¹⁸ F labelled Radioactive diagnostic agent	PET imaging of the brain to estimate β -amyloid neuritic plaque density in patients who are being evaluated for Alzheimer's disease	10/25/2013	S
20 Eslicarbazepine acetate (Aptiom)	Sunovion Pharms	MOA unknown, but thought to involve voltage-gated sodium channels	Partial-onset seizures	11/08/2013	S
21 Ibrutinib (Imbruvica)	Pharmacyclics	Bruton's tyrosine kinase inhibitor	Mantle cell lymphoma	11/13/2013	P, O
22 Luliconazole (Luzu)	Bausch	Azole antifungal, MOA unknown, but thought to inhibit the enzyme lanosterol demethylase	Interdigital tinea pedis, tinea cruris and tinea corporis caused by <i>Trichophyton rubrum</i> and <i>Epidermophyton floccosum</i>	11/14/2013	S
23 Simeprevir sodium (Olysio)	Janssen Prods	HCV NS3/4A protease inhibitor	Chronic HCV infection, as a component of a combination antiviral treatment regimen	11/22/2013	P
24 Sofosbuvir (Sovaldi)	Gilead Sciences	HCV nucleotide analogue NS5B polymerase inhibitor	Chronic HCV infection, as a component of a combination antiviral treatment regimen	12/06/2013	P
25 Umeclidinium bromide; Vilanterol trifenate (Anoro ellipta)	GlaxoSmithKline	Anticholinergic plus long-acting β 2-adrenergic agonist	Chronic obstructive pulmonary disease	12/18/2013	S
2013 Biologics license applications = 2					
1 Adu-trastuzumab emtansine (Kadcyla)	Genentech	HER2-directed ADC	HER2-positive metastatic breast cancer	02/22/2013	P
2 Obinutuzumab (Gazyva)	Genentech	CD20-directed mAb	Previously untreated chronic lymphocytic leukemia	11/01/2013	P, O

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2014 New molecular entities = 30					
1 Dapagliflozin (Farxiga)	AstraZeneca	Sodium-dependent glucose cotransporter 2 (SGLT2) inhibitor	Type 2 diabetes	01/08/2014	S
2 Tasimelteon (Hetlioz)	Vanda Pharms	Melatonin-receptor agonist	Non-24-hour sleep-wake disorder	01/31/2014	P, O
3 Droxidopa (Northera)	Lundbeck	Synthetic amino-acid precursor of noradrenaline; α -adrenergic receptors agonist	Light-headedness in patients with neurogenic orthostatic hypotension	02/18/2014	P, O
4 Florbetaben F-18 (Neuraceq)	Life Molecular	^{18}F labelled radioactive diagnostic agent	Imaging of the brain to estimate density of neuritic amyloid- β plaques	03/19/2014	S
5 Miltefosine (Impavido)	Knight Theraps	Antileishmanial agent, MOA unknown	Leishmaniasis	03/19/2014	P, O
6 Apremilast (Otezla)	Amgen	Phosphodiesterase 4 (PDE4) inhibitor	Psoriatic arthritis and plaque psoriasis	03/21/2014	S
7 Ceritinib (Zykadia)	Novartis	Multi-target TKI (ALK, IGF1R, INSR, and ROS1)	ALK-positive metastatic NSCLC	04/29/2014	P, O
8 Vorapaxar sulfate (Zontivity)	Xspire Pharma	Protease-activated receptor 1 antagonist	Thrombotic cardiovascular events	05/08/2014	S
9 Dalbavancin HCl (Dalvance)	Allergan	Semi-synthetic lipoglycopeptide, bacterial cell wall biosynthesis inhibitor	Acute bacterial skin and skin structure infections (ABSSSI)	05/23/2014	P
10 Efinacozole (Jublia)	Bausch	Azole antifungal, fungal lanosterol 14 α -demethylase inhibitor	Onychomycosis of the toenails	06/06/2014	S
11 Tedizolid phosphate (Sivextro)	Cubist	Oxazolidinone-class antibacterial, bacterial protein synthesis inhibitor	Acute bacterial skin and skin structure infections (ABSSSI)	06/20/2014	P
12 Belinostat (Beleodaq)	Acrotech	Histone-deacetylase inhibitor	Peripheral T-cell lymphoma	07/03/2014	P, O
13 Tavaborole (Kerydin)	Anacor Pharms	Oxaborole antifungal, cellular protein synthesis inhibitor	Onychomycosis of the toenails	07/07/2014	S
14 Idelalisib (Zydelig)	Gilead Sciences	PI3K δ inhibitor	Chronic lymphocytic leukaemia (CLL), B-cell non-Hodgkin's lymphoma, and small lymphocytic lymphoma (SLL)	07/23/2014	P, O
15 Olodaterol HCl (Striverdi respimat)	Boehringer Ingelheim	Long-acting β 2-adrenoceptor agonist	Chronic obstructive pulmonary disease (COPD)	07/31/2014	S
16 Empagliflozin (Jardiance)	Boehringer Ingelheim	Sodium-dependent glucose cotransporter 2 (SGLT2) inhibitor	Type 2 diabetes	08/01/2014	S
17 Oritavancin diphosphate (Orbactiv)	Melinta Therap	Semi-synthetic lipoglycopeptide, bacterial cell wall biosynthesis inhibitor	Acute bacterial skin and skin structure infections (ABSSSI)	08/06/2014	P
18 Suvorexant (Belsomra)	Merck & Co	Orexin-receptor antagonist	Insomnia	08/13/2014	S
19 Eliglustat tartrate (Cerdelga)	Genzyme	Glucosylceramide-synthase inhibitor	Gaucher's disease	08/19/2014	P, O
20 Naloxegol oxalate (Movantik)	Redhill	Opioid-receptor antagonist	Opioid-induced constipation	09/16/2014	S
21 Sulfur hexafluoride lipid-type A microspheres (Lumason)	Bracco	Ultrasound contrast agent	Cardiovascular imaging	10/10/2014	S
22 Netupitant; Palonosetron HCl (Aknzeo)	Helsinn Hlthcare	NK1-receptor antagonist plus 5-HT $_3$ receptor antagonist	Chemotherapy-related nausea	10/10/2014	S
23 Ledipasvir; Sofosbuvir (Harvoni)	Gilead Sciences	NS5A inhibitor plus HCV nucleotide-analog NS5B-polymerase inhibitor	Genotype 1 HCV	10/10/2014	P
24 Pirfenidone (Esbriet)	Genentech	MOA unknown	Idiopathic pulmonary fibrosis (IPF)	10/15/2014	P, O
25 Nintedanib esylate (Ofev)	Boehringer Ingelheim	Multi-kinase inhibitor (PDGFRs, FGFRs, VEGFRs, and FLT3)	Idiopathic pulmonary fibrosis (IPF)	10/15/2014	P, O
26 Finafloxacin (Xtoro)	Merlion Pharms	Fluoroquinolone antimicrobial	Acute otitis externa (Swimmer's ear)	12/17/2014	P
27 Olaparib (Lynparza)	AstraZeneca	PARP inhibitor	Advanced BRCA-mutated ovarian cancer	12/19/2014	P, O
28 Peramivir (Rapivab)	BioCryst	Neuraminidase inhibitor	Influenza infection	12/19/2014	S
29 Dasabuvir sodium; Ombitasvir; Paritaprevir; Ritonavir (Viekira pak [(Copackaged)])	AbbVie	NS5A inhibitor plus NS3A/4A-protease inhibitor plus non-nucleoside NS5B palm-polymerase inhibitor plus CYP3A inhibitor	Chronic HCV genotype 1 infection	12/19/2014	P
30 Ceftolozane sulfate; Tazobactam sodium (Zerbaxa)	Cubist Pharms	Cephalosporin antibacterial plus β -lactamase inhibitor	Complicated intra-abdominal infections and complicated urinary tract infections	12/19/2014	P
2014 Biologics license applications = 11					
1 Elosulfate alfa (Vimizim)	BioMarin Pharm	Recombinant human lysosomal glycosaminoglycan-specific enzyme	Mucopolysaccharidosis type IV A	02/14/2014	P, O
2 Metreleptin (Mylept)	Aegerion	Recombinant analog of the human hormone leptin	Leptin deficiency in patients with congenital or acquired generalized lipodystrophy	02/24/2014	P, O
3 Albiglutide (Tanzeum)	GlaxoSmithKline	Glucagon-like peptide 1 (GLP1) receptor agonist	Type 2 diabetes	04/15/2014	S
4 Ramucirumab (Cyramza)	Eli Lilly & Co	VEGFR2-directed mAb	Gastric cancer	04/21/2014	P, O
5 Siltuximab (Sylvant)	Janssen Biotech	Interleukin-6 (IL-6)-directed mAb	Multicentric Castlemans disease	04/23/2014	P, O
6 Vedolizumab (Entyvio)	Takeda	Integrin receptor antagonist	Ulcerative colitis and Crohn's disease	05/20/2014	P
7 Peginterferon β -1a (Plegridy)	Biogen Idec	Long-acting interferon β -1a	Relapsing multiple sclerosis	08/15/2014	S

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2014 Biologics license applications = 11					
8 Pembrolizumab (Keytruda)	Merck & Co	PD1-directed mAb	Metastatic melanoma	09/04/2014	P, O
9 Dulaglutide (Trulicity)	Eli Lilly & Co	GLP1-receptor agonist, recombinant dimeric fusion protein consisting of GLP1 peptide and Fc portion of human IgG4	Type 2 diabetes	09/18/2014	S
10 Blinatumomab (Blincyto)	Amgen	CD19- and CD3-bispecific mAb	B-cell precursor acute lymphoblastic leukemia (ALL)	12/03/2014	P, O
11 Nivolumab (Opdivo)	Bristol-Myers Squibb	PD1-directed mAb	Unresectable or metastatic melanoma	12/22/2014	P, O

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2015 New molecular entities = 32					
1 Edoxaban tosylate (Savaysa)	Daichi Sankyo	Factor Xa inhibitor	Risk of stroke and systemic embolism in NVAf, and deep vein thrombosis	01/08/2015	S
2 Palbociclib (Ibrance)	Pfizer	Cyclin-dependent kinase 4/6 (CDK4/6) inhibitor	HER2-negative and HR-positive advanced or metastatic breast cancer	02/03/2015	P
3 Lenvatinib mesylate (Lenvima)	Eisai	Multi-target TKI (VEGFRs, FGFRs, PDGFR α , RET, and KIT)	Thyroid cancer	02/13/2015	P, O
4 Panobinostat lactate (Farydak)	Secura	Histone deacetylase inhibitor	Multiple myeloma	02/23/2015	P, O
5 Avibactam sodium; Ceftazidime (Avycaz)	Allergan	β -lactamase inhibitor plus cephalosporin	Complicated intra-abdominal infections and complicated urinary tract infections	02/25/2015	P
6 Isavuconazonium sulfate (Cresemba)	Astellas	Azole antifungal, sterol 14- α -demethylase inhibitor	Invasive aspergillosis and mucormycosis	03/06/2015	P, O
7 Cholic acid (Cholbam)	Travere	Primary bile acid	Bile acid synthesis disorders and peroxisomal disorders	03/17/2015	P, O
8 Ivabradine HCl (Corlanor)	Amgen	Hyperpolarization-activated cyclic nucleotide-gated channel blocker	Chronic heart failure	04/15/2015	P
9 Deoxycholic acid (Kybella)	Kythera Biopharms	Cytolytic drug	Fat below the chin	04/29/2015	S
10 Eluxadolone (Viberzi)	Allergan Holdings	μ -opioid receptor agonist	Irritable bowel syndrome	05/27/2015	P
11 Cangrelor (Kengreal)	Chiesi	P2Y12 platelet inhibitor	Myocardial infarction, repeat coronary revascularization, and stent thrombosis	06/22/2015	S
12 Ivacaftor; Lumacaftor (Orkambi)	Vertex Pharms	CFTR potentiator plus CFTR corrector	Cystic fibrosis in patients with homozygous Δ F508 CFTR mutation	07/02/2015	P, O
13 Sacubitril; Valsartan (Entresto)	Novartis	Neprilysin inhibitor plus angiotensin II receptor blocker	Chronic heart failure	07/07/2015	P
14 Brexpiprazole (Rexulti)	Otsuka	Atypical antipsychotic, 5-HT $_{1A}$ and dopamine D2 receptors agonist, and 5-HT $_{2A}$ receptor antagonist	Major depressive disorder (MDD) and schizophrenia	07/10/2015	S
15 Sonidegib phosphate (Odomzo)	Sun Pharma Global	Smoothed inhibitor	Basal cell carcinoma	07/24/2015	S
16 Daclatasvir 2HCl (Daklinza)	Bristol-Myers Squibb	NS5A inhibitor	HCV infection	07/24/2015	P
17 Flibanserin (Addyi)	Sprout Pharms	Serotonin receptor modulator	Hypoactive sexual desire disorder	08/18/2015	S
18 Rolapitant HCl (Varubi)	Tersera	Neurokinin 1 receptor antagonist	Nausea and vomiting associated with chemotherapy	09/01/2015	S
19 Uridine triacetate (Xuriden)	Wellstat Therap	Pyrimidine analog, synthetic uridine prodrug	Hereditary orotic aciduria	09/04/2015	P, O
20 Cariprazine HCl (Vraylar)	Allergan	Atypical antipsychotic, 5-HT $_{1A}$ and dopamine D2 receptors agonist, and 5-HT $_{2A}$ receptor antagonist	Schizophrenia and bipolar 1 disorder	09/17/2015	S
21 Tipiracil HCl; Trifluridine (Lonsurf)	Taiho Oncology	Thymidine phosphorylase inhibitor plus a nucleoside metabolic inhibitor	Colorectal cancer	09/22/2015	S
22 Aripiprazole lauroxil (Aristada)	Alkermes	Atypical antipsychotic, 5-HT $_{1A}$ and dopamine D2 receptors agonist, and 5-HT $_{2A}$ receptor antagonist	Schizophrenia	10/05/2015	S
23 Patiromer sorbitex calcium (Veltassa)	Vifor Pharma	Potassium binder	Hyperkalemia	10/21/2015	S
24 Trabectedin (Yondelis)	Janssen Prods	Alkylating drug, interacts with the minor groove of DNA	Liposarcoma or leiomyosarcoma	10/23/2015	P, O
25 Cobicistat; Elvitegravir; Emtricitabine; Tenofovir alafenamide fumarate (Genvoya)	Gilead Sciences	INSTI plus CYP3A inhibitor plus two nucleoside analog reverse transcriptase inhibitors	HIV-1 infection	11/05/2015	S
26 Cobimetinib fumarate (Cotellic)	Genentech	MEK inhibitor	Melanoma with <i>BRAF</i> ^{V600E/K} mutations	11/10/2015	P, O
27 Osimertinib mesylate (Tagrisso)	AstraZeneca	EGFR inhibitor	NSCLC with <i>EGFR</i> ^{T790M} mutations	11/13/2015	P, O
28 Ixazomib citrate (Ninlaro)	Takeda	Oral proteasome inhibitor	Multiple myeloma	11/20/2015	P, O
29 Alectinib HCl (Alecensa)	Roche	ALK inhibitor	Non-small-cell lung cancer (NSCLC)	12/11/2015	P, O
30 Sugammadex sodium (Bridion)	Merck & Co	Modified γ -cyclodextrin	Reversal of neuromuscular blockade during surgery	12/15/2015	P
31 Selexipag (Uptravi)	Actelion	Prostacyclin receptor agonist	Pulmonary arterial hypertension	12/21/2015	S, O
32 Lesinurad (Zurampic)	Ironwood Pharms	Uric acid transporter 1 (URAT1) inhibitor	Gout	12/22/2015	S
2015 Biologics license applications = 13					
1 Secukinumab (Cosentyx)	Novartis	Interleukin-17A (IL-17A)-directed mAb	Plaque psoriasis	01/21/2015	S
2 Parathyroid hormone (Natpara)	NPS Pharma	Human parathyroid hormone (PTH) analog	Hypocalcemia in patients with hypoparathyroidism	01/23/2015	S, O
3 Dinutuximab (Unituxin)	United Therap	GD2-directed mAb	High-risk neuroblastoma	03/10/2015	P, O
4 Alirocumab (Praluent)	Sanofi	Proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor	Heterozygous familial hypercholesterolemia	07/24/2015	P
5 Evolocumab (Repatha)	Amgen	PCSK9 inhibitor	Primary hyperlipidemia	08/27/2015	S, O
6 Insulin degludec (Tresiba)	Novo Nordisk	Recombinant human insulin [Lys (B28), Pro (B29)]	Type 1 & 2 diabetes	09/25/2015	S

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2015 Biologics license applications = 13					
7 Idarucizumab (Praxbind)	Boehringer Ingelheim	Humanized anti-dabigatran IgG1κ Fab	Reversal of anticoagulant effects of dabigatran	10/16/2015	P, O
8 Asfotase alfa (Strensiq)	Strensiq	Human recombinant tissue-nonspecific alkaline phosphatase-Fc-deca-aspartate fusion protein	Hypophosphatasia	10/23/2015	P, O
9 Mepolizumab (Nucala)	GlaxoSmithKline	Interleukin-5 (IL-5)-directed mAb	Severe asthma	11/04/2015	S
10 Daratumumab (Darzalex)	Janssen Biotech	CD38-directed mAb	Multiple myeloma	11/16/2015	P, O
11 Necitumumab (Portrazza)	Eli Lilly & Co	EGFR-directed mAb	Non-small-cell lung cancer (NSCLC)	11/24/2015	S, O
12 Elotuzumab (Empliciti)	Bristol-Myers Squibb	SLAMF7-directed mAb	Multiple myeloma	11/30/2015	P, O
13 Sebelipase alfa (Kanuma)	Alexion Pharm	Recombinant human lysosomal acid lipase	Lysosomal acid lipase deficiency	12/08/2015	P, O

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2016 New molecular entities = 15					
1 Elbasvir; Grazoprevir (Zepatier)	Merck & Co	NS5A inhibitor plus NS3/4A protease inhibitor	HCV genotypes 1 and 4	01/28/2016	P
2 Brivaracetam (Briviact)	UCB	Anticonvulsant with unknown MOA, binds to SV2A	Partial-onset seizures	02/18/2016	S
3 Defibrotide sodium (Defitelio)	Jazz	Profibrinolytic	Hepatic veno-occlusive disease	03/30/2016	P, O
4 Venetoclax (Venclexta)	AbbVie	BCL-2 inhibitor	Chronic lymphocytic leukemia	04/11/2016	P, O
5 Pimavanserin tartrate (Nuplazid)	Acadia Pharms	Atypical antipsychotic, 5-HT _{2A} receptor antagonist	Hallucinations and delusions associated with Parkinson's disease psychosis	04/29/2016	P
6 Obeticholic acid (Ocaliva)	Intercept Pharms	Bile acid analog and farnesoid X receptor agonist	Primary biliary cholangitis	05/27/2016	P, O
7 Fluciclovine F-18 (Axumin)	Blue Earth	¹⁸ F labelled radioactive diagnostic agent	Imaging diagnosis of suspected prostate cancer recurrence	05/27/2016	P
8 Gallium dotatate Ga-68 (Netspot)	AAA USA Inc	⁶⁸ Ga labelled radioactive diagnostic	Imaging diagnosis of neuroendocrine tumors	06/01/2016	P, O
9 Sofosbuvir; Velpatasvir (Epclusa)	Gilead Sciences	Nucleotide analog NS5B polymerase inhibitor plus HCV NS5A inhibitor	HCV genotypes 1-6	06/28/2016	P
10 Lifitegrast (Xiidra)	Novartis	Tetrahydroisoquinoline derivative and lymphocyte function-associated antigen-1 (LFA1) antagonist	Dry eye disease	07/11/2016	P
11 Lixisenatide (Adlyxin)	Sanofi	Glucagon-like peptide-1 (GLP-1) receptor agonist	Type 2 diabetes	07/27/2016	S
12 Eteplirsen (Exondys 51)	Sarepta Theraps	Antisense oligonucleotide designed to target dystrophin pre-mRNA	Duchenne muscular dystrophy	09/19/2016	P, O
13 Crisaborole (Eucrisa)	Anacor Pharms	PDE4 inhibitor	Atopic dermatitis	12/14/2016	S
14 Rucaparib camsylate (Rubraca)	Clovis Oncology	PARP inhibitor	BRCA-positive ovarian cancer	12/19/2016	P, O
15 Nusinersen sodium (Spinraza)	Biogen Idec	Antisense oligonucleotide designed to target SMN2 pre-mRNA	Spinal muscular atrophy	12/23/2016	P, O
2016 Biologics license applications = 7					
1 Obiltoximab (Anthem)	Elusys Therapeutics	Anthrax toxin-directed mAb	Anthrax	03/18/2016	S, O
2 Ixekizumab (Taltz)	Eli Lilly & Co	Interleukin-17A (IL-17A)-directed mAb	Plaque psoriasis	03/22/2016	S
3 Reslizumab (Cinqair)	Teva	Interleukin-5 (IL-5)-directed mAb	Severe asthma	03/23/2016	S
4 Atezolizumab (Tecentriq)	Genentech	PDL1-directed mAb	Advanced or metastatic urothelial carcinoma	05/18/2016	P
5 Daclizumab (Zinbryta)	Biogen	Interleukin-2 (IL-2)-directed mAb	Multiple sclerosis	05/27/2016	S
6 Olaratumab (Lartruvo)	Eli Lilly & Co	PDGFR α -directed mAb	Soft tissue sarcoma	10/19/2016	P, O
7 Bezlotoxumab (Zinplava)	Merck & Co	<i>Clostridium difficile</i> toxin-directed mAb	<i>C. difficile</i> recurrence	10/21/2016	P

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2017 New molecular entities = 34					
1 Plecanatide (Trulance)	Salix	Guanylate cyclase C agonist	Chronic idiopathic constipation	01/19/2017	S
2 Etelcalcetide (Parsabiv)	Kai Pharms Inc	Calcium-sensing receptor agonist	Secondary hyperparathyroidism in patients with chronic kidney disease on hemodialysis	02/07/2017	S
3 Deflazacort (Emflaza)	PTC Therap	Corticosteroid	Duchenne muscular dystrophy	02/09/2017	P, O
4 Telotristat etiprate (Xermelo)	Tersera	Tryptophan hydroxylase inhibitor	Carcinoid syndrome diarrhea	02/28/2017	P, O
5 Ribociclib succinate (Kisqali)	Novartis	CDK4/6 inhibitor	HR-positive, HER2-negative breast cancer	03/13/2017	P
6 Safinamide mesylate (Xadago)	MDD US	MAO-B inhibitor	Parkinson's disease	03/21/2017	S
7 Naldemedine tosylate (Symproic)	BDSI	Opioid antagonist	Opioid-induced constipation	03/23/2017	S
8 Niraparib tosylate (Zejula)	GlaxoSmithKline	Poly-ADP ribose polymerase (PARP) inhibitor	Epithelial ovarian, fallopian tube or primary peritoneal cancer	03/27/2017	P, O
9 Deutetrabenazine (Austedo)	Teva	VMAT2 inhibitor	Chorea associated with Huntington disease	04/03/2017	S, O
10 Valbenazine tosylate (Ingrezza)	Neurocrine	VMAT2 inhibitor	Tardive dyskinesia	04/11/2017	P
11 Abaloparatide (Tymlos)	Radius Health	Parathyroid hormone-related protein	Osteoporosis	04/28/2017	S
12 Brigatinib (Alunbrig)	Takeda	Multi-target TKI (ALK, EGFR, IGF1R, FLT3, and ROS1)	ALK-positive NSCLC	04/28/2017	P, O
13 Midostaurin (Rydapt)	Novartis	Fms-like tyrosine kinase 3 (FLT3) inhibitor	FLT3-positive acute myeloid leukemia (AML)	04/28/2017	P, O
14 Edaravone (Radicava)	Mitsubishi Tanabe	MOA unknown (Free radical scavenger)	Amyotrophic lateral sclerosis (ALS)	05/05/2017	S, O
15 Delafloxacin meglumine (Baxdela)	Melinta	Fluoroquinolone antibacterial, bacterial DNA gyrase (topoisomerase II) and DNA topoisomerase IV inhibitor	Acute bacterial skin and skin structure infections	06/19/2017	P
16 Betrixaban (Bevyxxa)	Portola Pharms	FXa inhibitor	Prophylaxis of venous thromboembolism	06/23/2017	P
17 Neratinib maleate (Nerlynx)	Puma Biotech	EGFR, HER2, and HER4 inhibitor	HER2-overexpressed breast cancer	07/17/2017	S
18 Sofosbuvir; Velpatasvir; Voxilaprevir (Vosevi)	Gilead Sciences	Nucleotide analog NS5B polymerase inhibitor plus NS5A inhibitor plus NS3/4A protease inhibitor	HCV	07/18/2017	P
19 Enasidenib mesylate (Idhifa)	Celgene Corp	IDH2 inhibitor	IDH2-mutated acute myeloid leukemia (AML)	08/01/2017	P, O
20 Glecaprevir; Pibrentasvir (Mavyret)	AbbVie	NS3/4A protease inhibitor plus NS5A inhibitor	HCV	08/03/2017	P
21 Benznidazole	Chemo Research	Nitroimidazole antimicrobial	Chagas disease	08/29/2017	P, O
22 Meropenem; Vaborbactam (Vabomere)	Rempex	Carbapenem antimicrobial plus a β -lactamase inhibitor	Complicated urinary tract infections	08/29/2017	P
23 Copanlisib 2HCl (Aliqopa)	Bayer	PI3K α / δ inhibitor	Follicular lymphoma (FL)	09/14/2017	P, O
24 Secnidazole (Solosec)	Lupin	Nitroimidazole antimicrobial	Bacterial vaginosis	09/15/2017	P
25 Abemaciclib (Verzenio)	Eli Lilly & Co	CDK4/6 inhibitor	HR-positive, HER2-negative breast cancer	09/28/2017	P
26 Acalabrutinib (Calquence)	AstraZeneca	BTK inhibitor	Mantle cell lymphoma	10/31/2017	P, O
27 Latanoprostene bunod (Vyzulta)	Bausch & Lomb	Prostaglandin analog	Intraocular pressure	11/02/2017	S
28 Letemovir (Prevymis)	Merck & Co	CMV DNA terminase complex inhibitor	Prophylaxis of CMV	11/08/2017	P, O
29 Semaglutide (Ozempic)	Novo Nordisk	GLP1 receptor agonist	Type 2 diabetes	12/05/2017	S
30 Ozenoxacin (Xepi)	Ferrer Internacional	Quinolone antimicrobial	Impetigo due to <i>Staphylococcus aureus</i> or <i>Streptococcus pyogenes</i>	12/11/2017	S
31 Netarsudil mesylate (Rhopressa)	Aerie Pharms	RHO kinase inhibitor	Open-angle glaucoma or ocular hypertension	12/18/2017	P
32 Ertugliflozin (Steglatro)	Merck & Co	Sodium-dependent glucose cotransporter 2 (SGLT2) inhibitor	Type 2 diabetes	12/19/2017	S
33 Macimorelin acetate (Macrilen)	Novo Nordisk	Growth hormone secretagogue receptor agonist	Diagnosis of adult growth hormone deficiency	12/20/2017	S, O
34 Angiotensin II acetate (Giapreza)	La Jolla Pharma	Synthetic human angiotensin	Blood pressure in adults with septic or other distributive shock	12/21/2017	P
2017 Biologics license applications = 12					
1 Brodalumab (Siliq)	Valeant Luxembourg	IL-17RA-directed mAb	Plaque psoriasis	02/15/2017	S
2 Avelumab (Bavencio)	Emd Serono	PDL1-directed mAb	Merkel cell carcinoma	03/23/2017	P, O
3 Ocrelizumab (Ocrevus)	Genentech	CD20-directed mAb	Relapsing or primary progressive forms of multiple sclerosis	03/23/2017	P
4 Dupilumab (Dupixent)	Regeneron	Interleukin-4 (IL-4) receptor alpha (IL-4R α)-directed mAb	Atopic dermatitis	03/28/2017	P
5 Cerliponase alfa (Brineura)	BioMarin Pharm	Tripeptidyl peptidase	Tripeptidyl peptidase 1 deficiency	04/27/2017	P, O
6 Durvalumab (Imfinzi)	AstraZeneca	PDL1-directed mAb	Urothelial carcinoma	05/01/2017	P
7 Sarilumab (Kevzara)	Sanofi	Interleukin 6 (IL-6) receptor-directed mAb	Rheumatoid arthritis	05/22/2017	S

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2017 Biologics license applications = 12					
8 Guselkumab (Tremfya)	Janssen Biotech	Interleukin 23 (IL-23)-directed mAb	Plaque psoriasis	07/13/2017	P, O
9 Inotuzumab ozogamicin (Besponsa)	Wyeth Pharms	CD22-directed ADC	B cell precursor acute lymphoblastic leukemia (ALL)	08/17/2017	P, O
10 Benralizumab (Fasenra)	AstraZeneca	Interleukin-5 (IL-5) receptor alpha (IL-5R α)-directed mAb	Severe asthma	11/14/2017	S
11 Vestronidase alfa (Mepsevii)	Ultragenyx Pharm Inc	Recombinant human lysosomal β -glucuronidase	Mucopolysaccharidosis VII	11/15/2017	P, O
12 Emicizumab (Hemlibra)	Genentech	Bispecific FIX and FX-directed antibody	Hemophilia A	11/16/2017	P, O

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2018 New molecular entities = 42					
1 Lutetium dotatate Lu-177 (Lutathera)	AAA USA Inc	Somatostatin receptor-targeted radiopharmaceutical	Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)	01/26/2018	P, O
2 Bictegravir sodium; Emtricitabine; Tenofovir alafenamide fumarate (Biktarvy)	Gilead Sciences	HIV-1 integrase inhibitor plus HIV-1 nucleoside/nucleotide reverse transcriptase inhibitors	HIV-1 infection	02/07/2018	P
3 Tezacaftor; Ivacaftor (Symdeko)	Vertex Pharms	Cystic fibrosis transmembrane conductance regulator (CFTR) corrector and CFTR potentiator	Cystic fibrosis	02/12/2018	P, O
4 Apalutamide (Erleada)	Janssen Biotech	Androgen receptor inhibitor	Prostate cancer	02/14/2018	P
5 Fostamatinib disodium (Tavalisse)	Rigel Pharms	Spleen tyrosine kinase (SYK) inhibitor	Immune thrombocytopenic purpura	04/17/2018	S, O
6 Fosnetupitant chloride HCl; Palonosetron HCl (Akyzео IV)	Helsinn Group	Neurokinin 1 (NK1) receptor antagonist plus 5-HT ₃ receptor antagonist	Chemotherapy-induced nausea	04/19/2018	S
7 Lofexidine HCl (Lucemyra)	US WorldMeds	α ₂ -adrenoceptor agonist	Opioid withdrawal	05/16/2018	P
8 Sodium zirconium cyclosilicate (Lokelma)	AstraZeneca	Potassium binder	Hyperkalemia	05/18/2018	S
9 Avatrombopag maleate (Doptelet)	Akarx	Thrombopoietin receptor agonist	Thrombocytopenia	05/21/2018	P
10 Baricitinib (Olmiant)	Eli Lilly & Co	Reversible Janus kinase (JAK) inhibitor	Rheumatoid arthritis	05/31/2018	S
11 Moxidectin	MDGH	Anthelmintic GABA receptor and glutamate channel modulator	River blindness	06/13/2018	P, O
12 Plazomicin sulfate (Zemdri)	Cipla USA	Aminoglycoside antibacterial	Urinary tract infections	06/25/2018	P
13 Cannabidiol (Epidiolex)	GW Res Ltd	Cannabinoid	Dravet syndrome and Lennox-Gastaut syndrome	06/25/2018	P, O
14 Encorafenib (Braftovi)	Array BioPharma	BRAF inhibitor	BRAF-mutated melanoma	06/27/2018	S, O
15 Binimetinib (Mektovi)	Array BioPharma	MEK inhibitor	BRAF-mutated melanoma	06/27/2018	S, O
16 Tecovirimat (Tpoxx)	SIGA Technologies	Viral p37 protein inhibitor	Smallpox	07/13/2018	P, O
17 Tafenoquine succinate (Krintafel)	GlaxoSmithKline	8-Aminoquinoline antimalarial	Plasmodium vivax malaria	07/20/2018	P, O
18 Ivosidenib (Tibsovo)	Servier	Isocitrate dehydrogenase-1 (IDH1) inhibitor	IDH1-mutated acute myeloid leukemia (AML)	07/20/2018	P, O
19 Elagolix sodium (Orilissa)	AbbVie	GnRH receptor antagonist	Pain associated with endometriosis	07/23/2018	P
20 Fish oil triglycerides (Omegaven)	Fresenius Kabi USA	Mixture of fatty acids	Parenteral nutrition-associated cholestasis	07/27/2018	P, O
21 Lusutrombopag (Mupleta)	Shionogi Inc	Thrombopoietin receptor agonist	Thrombocytopenia	07/31/2018	P
22 Migalastat HCl (Galafold)	Amicus Therap US	α-galactosidase regulator	Fabry disease	08/10/2018	P, O
23 Ethinyl estradiol; Segesterone acetate (Annovera)	Therapeuticsmd	Estrogen and progestin combined hormonal contraceptive	Female contraception	08/10/2018	S
24 Patisiran sodium (Onpatro)	Alnylam Pharms	Transthyretin (TTR)-directed small interfering RNA	Hereditary TTR-mediated amyloidosis	08/10/2018	P, O
25 Stiripentol (Diacomit)	Biocodex	γ-aminobutyric acid (GABA) reuptake inhibitor	Dravet syndrome	08/20/2018	P, O
26 Eravacycline 2HCl (Xerava)	Tetraphase Pharms	Tetracycline antibiotic	Complicated intra-abdominal infections	08/27/2018	P
27 Doravirine (Pifeltro)	Merck & Co	Non-nucleoside reverse transcriptase inhibitor	HIV-1 infection	08/30/2018	S
28 Duvelisib (Copiktra)	Secura	Phosphatidylinositol 3-kinase δ/γ (PI3Kδ/γ) inhibitor	Chronic lymphocytic leukaemia (CLL), follicular lymphoma (FL), and small lymphocytic lymphoma (SLL)	09/24/2018	P, O
29 Dacomitinib (Vizimpro)	Pfizer	EGFR inhibitor	EGFR-mutated NSCLC	09/27/2018	P, O
30 Sarecycline HCl (Seysara)	Almirall	Tetracycline antibiotic	Severe acne vulgaris	10/01/2018	S
31 Omadacycline tosylate (Nuzyra)	Paratek Pharms	Tetracycline antibiotic	Community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infection (ABSSI)	10/02/2018	P
32 Inotersen sodium (Tegsedi)	Akcea Theraps	Transthyretin (TTR)-directed antisense oligonucleotide	Hereditary TTR-mediated amyloidosis	10/05/2018	P, O
33 Talazoparib tosylate (Talzenna)	Pfizer	Poly-ADP ribose polymerase (PARP) inhibitor	BRCA-mutated HER2-negative breast cancer	10/16/2018	P
34 Baloxavir marboxil (Xofluza)	Genentech	Polymerase acidic endonuclease inhibitor	Acute uncomplicated influenza	10/24/2018	P
35 Lorlatinib (Lorbrena)	Pfizer	Multi-target TKI (ALK and ROS1)	ALK-positive NSCLC	11/02/2018	P, O
36 Revefenacin (Yupelri)	Mylan Ireland	Long-acting muscarinic receptor antagonist	Chronic obstructive pulmonary disease (COPD)	11/09/2018	S
37 Rifamycin sodium (Aemcolo)	Cosmo Technologies	Ansamycin antibacterial	Travelers' diarrhea	11/16/2018	P
38 Glasdegib maleate (Daurismo)	Pfizer	Smoothed (Hedgehog pathway) inhibitor	Acute myeloid leukemia (AML)	11/21/2018	P, O
39 Larotrectinib sulfate (Vitrakvi)	Bayer	TRKs inhibitor	NTRK-positive solid cancers	11/26/2018	P, O
40 Amifampridine phosphate (Firdapse)	Catalyst Pharms	Potassium channel blocker	Lambert-Eaton myasthenic syndrome	11/28/2018	P, O
41 Gilteritinib fumarate (Xospata)	Astellas	Fms-like tyrosine kinase 3 (FLT3) inhibitor	FLT3-positive AML	11/28/2018	P, O

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
42 Prucalopride succinate (Motegrity)	Takeda Pharms USA	5-HT4 receptor agonist	Chronic idiopathic constipation	12/14/2018	S
2018 Biologics license applications = 17					
1 Ibalizumab (Trogarzo)	TaiMed Biologics USA	CD4-directed mAb	HIV-1 infection	03/06/2018	P, O
2 Tildrakizumab (Ilumya)	Sun Pharma Global	Interleukin-23 (IL-23)-directed mAb	Plaque psoriasis	03/20/2018	S
3 Burosumab (Crysvita)	Ultragenyx Pharm	Fibroblast growth factor 23 (FGF23)-directed mAb	X-linked hypophosphatemia	04/17/2018	P, O
4 Erenumab (Aimovig)	Amgen Inc	Calcitonin gene-related peptide receptor (CGRPR)-directed mAb	Migraine	05/17/2018	S
5 Pegvaliase (Palynziq)	BioMarin Pharm	Recombinant phenylalanine ammonia lyase (PAL) enzyme	Phenylketonuria	05/24/2018	P, O
6 Mogamulizumab (Poteligeo)	Kyowa Kirin	CC chemokine receptor 4 (CCR4)-directed mAb	Mycosis fungoides and Sézary syndrome	08/08/2018	P, O
7 Cenegermin (Oxervate)	Dompe Farmaceutici	Recombinant human nerve growth factor (NGF)	Neurotrophic keratitis	08/22/2018	P, O
8 Lanadelumab (Takhzyro)	Dyax Corp	Kallikrein-directed mAb	Hereditary angioedema	08/23/2018	P, O
9 Moxetumomab pasudotox (Lumoxiti)	Innate Pharma	CD22-directed ADC	Hairy cell leukemia	09/13/2018	P, O
10 Fremanezumab (Ajovy)	Teva Pharms USA	Calcitonin gene-related peptide (CGRP)-directed mAb	Migraine	09/14/2018	P
11 Galcanezumab (Emgality)	Eli Lilly & Co	Calcitonin gene-related peptide (CGRP)-directed mAb	Migraine	09/27/2018	S
12 Cemiplimab (Libtayo)	Regeneron Pharmaceuticals	Programmed death receptor-1 (PD1)-directed mAb	Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)	09/28/2018	P
13 Elapegedemase (Revcovi)	Leadiant Biosci	Recombinant human adenosine deaminase	Adenosine deaminase severe combined immune deficiency (ADA-SCID)	10/05/2018	P, O
14 Emapalumab (Gamifant)	Novimmune S.A.	Interferon-γ (INFγ)-directed mAb	Primary hemophagocytic lymphohistiocytosis	11/20/2018	P, O
15 Calaspargase pegol (Asparlas)	Servier Pharma	Asparagine specific enzyme	Acute lymphoblastic leukemia (ALL)	12/20/2018	S, O
16 Ravulizumab (Ultomiris)	Alexion Pharm	Complement 5 (C5)-directed mAb	Paroxysmal nocturnal hemoglobinuria	12/21/2018	S, O
17 Tagraxofusp (Elzonris)	Stemline Therapeutics	IL-3 and diphtheria toxin fusion protein	Blastic plasmacytoid dendritic cell neoplasm	12/21/2018	P, O

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2019 New molecular entities = 38					
1 Triclabendazole (Egaten)	Novartis	Anthelmintic, MOA unknown	Fascioliasis	02/13/2019	P, O
2 Brexanolone (Zulresso)	Sage Therap	γ-aminobutyric acid A (GABA _A) receptor- positive modulator	Postpartum depression	03/19/2019	P
3 Solriamfetol HCl (Sunosi)	Jazz	Dopamine and noradrenaline reuptake inhibitor	Excessive sleepiness due to narcolepsy or obstructive sleep apnea	03/20/2019	S, O
4 Siponimod fumaric acid (Mayzent)	Novartis	Sphingosine 1-phosphate (S1P) receptor modulator	Relapsing forms of multiple sclerosis	03/26/2019	S
5 Erdafitinib (Balversa)	Janssen Biotech	Fibroblast growth factor receptor (FGFR) inhibitor	Bladder cancer	04/12/2019	P
6 Tafamidis meglumine (Vyndaqel)	Foldrx Pharms	Transthyretin stabilizer	Heart disease caused by transthyretin amyloid cardiomyopathy (ATTR-CM)	05/03/2019	P, O
7 Alpelisib (Piqray)	Novartis	Phosphatidylinositol 3-kinase α (PI3Kα) inhibitor	Breast cancer	05/24/2019	P
8 Bremelanotide acetate (Vyleesi)	Palatin Technologies	Melanocortin receptor agonist	Hypoactive sexual desire disorder	06/21/2019	S
9 Selinexor (Xpovio)	Karyopharm Theraps	Exportin 1 (XPO1) inhibitor	Multiple myeloma	07/03/2019	P, O
10 Cilastatin sodium; Imipenem; Relebactam (Recarbrio)	Msd Merck Co	Renal dehydropeptidase inhibitor; Penem antibacterial; β-lactamase inhibitor	Complicated urinary tract and complicated intra-abdominal infections	07/16/2019	P
11 Ferric maltol (Accrufer)	Shield TX	Iron replacement product	Iron deficiency anemia	07/25/2019	S
12 Darolutamide (Nubeqa)	Bayer Healthcare	Androgen receptor inhibitor	Prostate cancer	07/30/2019	P
13 Pexidartinib HCl (Turalio)	Daiichi Sankyo Inc	CSF1R, KIT, and FLT3 inhibitor	Tenosynovial giant cell tumor	08/02/2019	P, O
14 Pitolisant HCl (Wakix)	Harmony	Histamine H3 receptor antagonist/inverse agonist	Excessive sleepiness due to narcolepsy	08/14/2019	P, O
15 Pretomanid (Pretomanid)	Mylan Ireland Ltd	Antimycobacterial	Tuberculosis	08/14/2019	P, O
16 Entrectinib (Rozlytrek)	Genentech Inc	Multi-target TKI (TRKs, ROS1, and ALK)	NTRK fusion- positive solid tumors and ROS1- positive NSCLC	08/15/2019	P, O
17 Upadacitinib (Rinvoq)	AbbVie Inc	JAK inhibitor	Rheumatoid arthritis	08/16/2019	S
18 Fedratinib HCl (Inrebic)	Impact	JAK2 and FLT3 inhibitor	Myelofibrosis	08/16/2019	P, O
19 Lefamulin acetate (Xenleta)	Nabriva	Pleuromutilin antibacterial	Community-acquired bacterial pneumonia (CABP)	08/19/2019	P
20 Gallium dotatoc Ga-68	UIHC PET Imaging	⁶⁸ Ga labelled radioactive diagnostic agent	Localization of somatostatin receptor-positive neuroendocrine tumors	08/21/2019	S, O
21 Istradefylline (Nourianz)	Kyowa Kirin	Adenosine receptor antagonist	Parkinson disease, 'off' episodes	08/27/2019	S
22 Tenapanor HCl (Ibsrela)	Ardelyx Inc	Sodium/hydrogen exchanger 3 (NHE3) inhibitor	Irritable bowel syndrome (IBS) with constipation	09/12/2019	S
23 Trifarotene (Aklief)	Galderma Labs Lp	Retinoic acid receptor agonist	Acne vulgaris	10/04/2019	S
24 Afamelanotide (Scenesse)	Clinuvel Inc	Melanocortin 1 receptor agonist	Erythropoietic protoporphyria	10/08/2019	P, O
25 Fluorodopa F-18	Feinstein	¹⁸ F labelled radioactive diagnostic agent	Diagnosis of parkinsonian syndromes	10/10/2019	S
26 Lasmiditan succinate (Reyvow)	Eli Lilly & Co	5-HT _{1F} receptor agonist	Migraine with or without aura	10/11/2019	S
27 Tezacaftor; Elexacaftor; Ivacaftor (Trikafta)	Vertex Pharms Inc	Two cystic fibrosis transmembrane conductance regulator (CFTR) correctors and a CFTR potentiator	Most common gene mutation that causes cystic fibrosis	10/21/2019	P, O
28 Air polymer-type A (ExEm Foam kit)	Giskit	Ultrasound contrast agent	Assess fallopian tube patency in women with known or suspected infertility	11/07/2019	S
29 Cefiderocol sulfate tosylate (Fetroja)	Shionogi Inc	Cephalosporin antibacterial, inhibits cell wall synthesis	Complicated urinary tract infections	11/14/2019	P
30 Zanubrutinib (Brukinsa)	BeiGene	Bruton's tyrosine kinase (BTK) inhibitor	Mantle cell lymphoma	11/14/2019	P, O
31 Givosiran sodium (Givlaari)	Anylam Pharms Inc	5-aminolevulinic acid synthase (ALAS1)-directed siRNA	Acute hepatic porphyria	11/20/2019	P, O
32 Cenobamate (Xcopri)	SK Life	Voltage-gated sodium channel inhibitor and γ-aminobutyric acid A (GABA _A) receptor- positive modulator	Partial onset seizures	11/21/2019	S
33 Voxelotor (Oxbryta)	Global Blood Theraps	Hemoglobin S polymerization inhibitor	Sickle cell disease (SCD)	11/25/2019	P, O
34 Golodirsen (Vyondys 53)	Sarepta Theraps Inc	Exon 53 skipping antisense	Duchenne muscular dystrophy	12/12/2019	P, O
35 Lumateperone tosylate (Caplyta)	Intra-Cellular	Atypical antipsychotic	Schizophrenia	12/20/2019	S
36 Brilliant Blue G (Tissueblue)	Dutch Ophthalmic	Brilliant Blue G dye	Staining the internal limiting membrane	12/20/2019	P, O
37 Lemborexant (Dayvigo)	Eisai Inc	Orexin receptor antagonist	Insomnia	12/20/2019	S
38 Ubrogепant (Ubroelvy)	Allergan	Calcitonin gene- related peptide (CGRP) receptor antagonist	Migraine with or without aura	12/23/2019	S
2019 Biologics license applications = 10					
1 PrabotulinumtoxinA (Jeuveau)	Evolus Inc	Acetylcholine release inhibitor and a neuromuscular blocking agent	Glabella lines associated with corrugator and/or procerus muscle activity	02/01/2019	S
2 Caplacizumab (Cablivi)	Ablynx NV	von Willebrand factor (vWF)-directed nanobody	Acquired thrombotic thrombocytopenic purpura (ATTP)	02/06/2019	P, O

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2019 Biologics license applications = 10					
3 Romosozumab (Evenity)	Amgen Inc	Sclerostin-directed mAb	Osteoporosis	04/09/2019	S
4 Risankizumab (Skyrizi)	AbbVie Inc	Interleukin-23 (IL-23)-directed mAb	Plaque psoriasis	04/23/2019	S
5 Polatuzumab vedotin (Polivy)	Genentech	CD79b-directed antibody-drug conjugate (ADC)	Diffuse large B-cell lymphoma	06/10/2019	P, O
6 Brolucizumab (Beovu)	Novartis	VEGFA-directed antibody-drug conjugate (ADC)	Wet age-related macular degeneration	10/07/2019	S
7 Luspatercept (Reblozyl)	Celgene	Recombinant fusion protein comprised of modified extracellular domain of activin receptor type IIB and FC domain of human IgG1	Anemia in β -thalassemia	11/08/2019	P, O
8 Crizanlizumab (Adakveo)	Novartis	P-selectin blocker	Painful complications of sickle cell disease (SCD)	11/15/2019	P, O
9 Enfortumab vedotin (Padcev)	Astellas	Nectin-4-directed antibody-drug conjugate (ADC)	Urothelial carcinoma	12/18/2019	P
10 Trastuzumab deruxtecan (Enhertu)	Daiichi Sankyo	HER2-directed antibody-drug conjugate (ADC)	HER2-positive breast cancer	12/20/2019	P

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2020 New molecular entities = 40					
1 Avapritinib (Ayvakit)	Blueprint Medicines	PDGFR α , PDGFR α mutants, and KIT inhibitor	Gastrointestinal stromal tumor (GIST) with <i>PDGFRA</i> exon 18 mutations	01/09/2020	P, O
2 Tazemetostat (Tazverik)	Epizyme Inc	Enhancer of Zeste Homolog 2 (EZH2) inhibitor	Epithelioid sarcoma	01/23/2020	P, O
3 Lactitol (Pizensy)	Braintree Labs	Osmotic laxative	Chronic idiopathic constipation	02/12/2020	S
4 Bempedoic acid (Nexletol)	Esperion Therapeutics	Adenosine triphosphate-citrate lyase (ACL) inhibitor	Heterozygous familial hypercholesterolemia (HeFH) or atherosclerotic cardiovascular disease	02/21/2020	S
5 Amisulpride (Barhemsys)	Acacia	Dopamine D2 receptor antagonist	Nausea and vomiting after surgery	02/26/2020	S
6 Rimegepant sulfate (Nurtec ODT)	Biohaven	Calcitonin gene-related peptide (CGRP) receptor antagonist	Migraine	02/27/2020	S
7 Osilodrostat phosphate (Isturisa)	Recordati Rare Diseases	Cortisol synthesis inhibitor	Cushing's disease	03/06/2020	S, O
8 Ozanimod HCl (Zeposia)	Celgene	Sphingosine 1-phosphate (S1P) receptor modulator	Multiple sclerosis	03/25/2020	S
9 Selumetinib sulfate (Koselugo)	AstraZeneca	MEK1/2 kinase inhibitor	Neurofibromatosis type 1	04/10/2020	P, O
10 Tucatinib (Tukysa)	Seagen	HER2 inhibitor	HER2-positive breast cancer	04/17/2020	P, O
11 Pemigatinib (Pemazyre)	Incyte	Fibroblast growth factor receptor 1-3 (FGFR1-3) kinase inhibitor	Advanced cholangiocarcinoma with <i>FGFR2</i> fusions/rearrangements	04/17/2020	P, O
12 Opicapone (Ongentys)	Neurocrine	Catechol-O-methyltransferase (COMT) inhibitor	Parkinson's disease	04/24/2020	S
13 Capmatinib HCl (Tabrecta)	Novartis	MET kinase inhibitor	Non-small-cell lung cancer (NSCLC)	05/06/2020	P, O
14 Selpercatinib (Retevmo)	Loxo Oncology	RET kinase inhibitor	RET fusion-positive NSCLC and thyroid cancer	05/08/2020	P, O
15 Ripretinib (Qinlock)	Deciphera	PDGFR α , PDGFR α mutants, and KIT inhibitor	Advanced gastrointestinal stromal tumor (GIST)	05/15/2020	P, O
16 Fluoroestradiol F-18 (Cerianna)	Zionexa	¹⁸ F labelled radioactive diagnostic agent	Imaging, breast cancer	05/20/2020	S
17 Artesunate	Amivas	Artemisinin antimalarial	Severe malaria	05/26/2020	P, O
18 Flortaucipir F-18 (Tauvid)	Avid Radiopharms	¹⁸ F labelled radioactive diagnostic agent	Imaging, tau in Alzheimer's disease	05/28/2020	P
19 Lurbinectedin (Zepzelca)	Jazz	DNA alkylating drug	Small-cell lung cancer	06/15/2020	P, O
20 Triheptanoin (Dojolvi)	Ultragenyx	Medium-chain triglyceride	Long chain fatty acid oxidation disorders (LC-FAODs)	06/30/2020	S, O
21 Remimazolam besylate (Byfavo)	Acacia	Benzodiazepine	Procedural sedation	07/02/2020	S
22 Fostemsavir tromethamine (Rukobia)	Viiv Healthcare	HIV-1 attachment inhibitor	HIV-1 infection	07/02/2020	P
23 Cedazuridine; Decitabine (Inqovi)	Otsuka	Cytidine deaminase inhibitor; Nucleoside metabolic inhibitor	Myelodysplastic syndromes	07/07/2020	P, O
24 Abametapir (Xeglyze)	Dr Reddy's	Metalloproteinase inhibitor	Head lice	07/24/2020	S
25 Nifurtimox (Lampit)	Bayer	Nitrofurant antiprotozoal	Chagas disease	08/06/2020	P, O
26 Oliceridine (Olinvyk)	Trevena	Opioid receptor agonist	Acute pain	08/07/2020	S
27 Risdiplam (Evryso)	Genentech	Survival of motor neuron 2 (SMN2) splicing modifier	Spinal muscular atrophy	08/07/2020	P, O
28 Viltolarsen (Viltepso)	Nippon Shinyaku	Dystrophin splicing modifier	Duchenne muscular dystrophy	08/12/2020	P, O
29 Clascoterone (Winlevi)	Sun Pharm	Androgen receptor inhibitor	Acne vulgaris	08/26/2020	S
30 Copper dotatate Cu-64 (Detectnet)	Radiomedix	⁶⁴ Cu labelled somatostatin analog	Imaging, cancer	09/03/2020	P, O
31 Pralsetinib (Gavreto)	Genentech	RET kinase inhibitor	RET fusion-positive NSCLC	09/04/2020	P, O
32 Remdesivir (Veklury)	Gilead Sciences	Nucleotide analog RNA polymerase inhibitor	COVID-19 infection	10/22/2020	P
33 Lonafarnib (Zokinvy)	Eiger Biopharms	Farnesyltransferase inhibitor	Hutchinson-Gilford progeria syndrome (HGPS)	11/20/2020	P, O
34 Lumasiran sodium (Oxlumo)	Alnylam	Hydroxyacid oxidase 1 (HAO1)-directed siRNA	Hyperoxaluria type 1	11/23/2020	P, O
35 Setmelanotide acetate (Imcivree)	Rhythm	Melanocortin 4 (MC4) receptor agonist	Rare genetic diseases of obesity	11/25/2020	P, O
36 PSMA-11 Ga-68	UCLA	⁶⁸ Ga labelled radioactive diagnostic agent	Imaging, prostate cancer	12/01/2020	S
37 Berotralstat HCl (Orladeyo)	BioCryst	Plasma kallikrein inhibitor	Hereditary angioedema	12/03/2020	S, O
38 Tirbanibulin (Klisyri)	Almirall	Microtubule inhibitor	Actinic keratosis	12/14/2020	S
39 Relugolix (Orgovyx)	Myovant Sciences	GnRH receptor antagonist	Prostate cancer	12/18/2020	P
40 Vibegron (Gemtesa)	Urovant Sciences	β 3-adrenoceptor agonist	Overactive bladder	12/23/2020	S
2020 Biologics license applications = 13					
1 Teprotumumab (Tepezza)	Horizon Therapeutics	Insulin-like growth factor-1 receptor (IGF1R)-directed mAb	Thyroid eye disease	01/21/2020	P, O
2 Eptinezumab (Vyepti)	Lundbeck	Calcitonin gene-related peptide (CGRP)-directed mAb	Migraine	02/21/2020	S

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2020 Biologics license applications = 13					
3 Isatuximab (Sarclisa)	Sanofi	CD38-directed mAb	Multiple myeloma	03/02/2020	S, O
4 Sacituzumab govitecan (Trodelvy)	Immunomedics Inc	Trophoblast cell surface antigen 2 (Trop2)-directed ADC	Triple-negative breast cancer	04/22/2020	P
5 Inebilizumab (Uplizna)	Vielia Bio	CD19-directed mAb	Neuromyelitis optica spectrum disorder (NMOSD)	06/11/2020	S, O
6 Tafasitamab (Monjuvi)	MorphoSys	CD19-directed mAb	Diffuse large B-cell lymphoma (DLBCL)	07/31/2020	P, O
7 Belantamab mafodotin (Blenrep)	GlaxoSmithKline	B-cell maturation antigen (BCMA)-directed ADC	Multiple myeloma	08/05/2020	P, O
8 Satralizumab (Enspryng)	Genentech	Interleukin-6 receptor (IL-6R)-directed mAb	Neuromyelitis optica spectrum disorder (NMOSD)	08/14/2020	S, O
9 Somapacitan (Sogroya)	Novo Nordisk	Growth hormone analog	Growth hormone deficiency	08/28/2020	S
10 Atoltivimab; Odesivimab; Maftivimab (Inmazeb)	Jazz	Cocktail of Ebola glycoprotein-directed mAbs	Ebola virus	10/14/2020	P, O
11 Naxitamab (Danyelza)	Y-mAbs Therapeutics	GD2-directed mAb	High-risk neuroblastoma	11/25/2020	P, O
12 Margetuximab (Margenza)	MacroGenics	HER2-directed mAb	HER2-positive breast cancer	12/16/2020	S
13 Ansuvimab (Ebanga)	Ridgeback	Ebola glycoprotein-directed mAb	Ebola virus	12/21/2020	P, O

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2021 New molecular entities = 36					
1 Vericiguat (Verquvo)	Merck & Co	Soluble guanylate cyclase (sGC) stimulator	Chronic heart failure	01/19/2021	P
2 Cabotegravir; Rilpivirine (Cabenuva Kit)	Viiv Hlthcare	Integrase strand transfer inhibitor (INSTI) and non-nucleoside reverse transcriptase inhibitor (NNRTI) of HIV-1	HIV-1 infection	01/21/2021	P
3 Voclosporin (Lupkynis)	Aurinia	Calcineurin inhibitor	Lupus nephritis	01/22/2021	P
4 Tepotinib HCl (Tepmetko)	Emd Serono	MET inhibitor	Non-small-cell lung cancer (NSCLC)	02/03/2021	P, O
5 Umbralisib tosylate (Ukoniq)	TG Theraps	PI3Kδ and CK1ε inhibitor	Relapsed or refractory marginal zone lymphoma (MZL), follicular lymphoma	02/05/2021	P, O
6 Trilaciclib 2HCl (Cosela)	G1 Therap	CDK4/6 kinase inhibitor	Chemotherapy-induced myelosuppression	02/12/2021	P
7 Casimersen (Amondys 45)	Sarepta	Exon 45-skipping antisense oligonucleotide (ASO)	Duchenne muscular dystrophy (DMD)	02/25/2021	P, O
8 Fosdenopterin HCl (Nulibry)	Origin	Cyclic pyranopterin monophosphate (cPMP)	Molybdenum cofactor deficiency (MoCD) type A	02/26/2021	P, O
9 Melphalan flufenamide HCl (Pepaxto)	Oncopeptides	Peptide-conjugated alkylating drug	Multiple myeloma	02/26/2021	P, O
10 Dexmethylphenidate HCl; Serdexmethylphenidate chloride (Azstarys)	Commave Therap	Central nervous system (CNS) stimulant	Attention deficit hyperactivity disorder (ADHD)	03/02/2021	S
11 Tivozanib HCl (Fotivda)	Aveo Pharms	VEGFRs inhibitor	Advanced renal cell carcinoma	03/10/2021	S
12 Ponesimod (Ponvory)	Janssen Pharms	Sphingosine 1- phosphate (S1P) receptor modulator	Relapsing multiple sclerosis	03/18/2021	S
13 Dasiglucagon HCl (Zegalogue)	Zealand Pharma	Glucagon receptor agonist	Severe hypoglycemia	03/22/2021	S
14 Viloxazine HCl (Qelbree)	Supernus	Selective norepinephrine reuptake inhibitor (NRI)	Attention deficit hyperactivity disorder (ADHD)	04/02/2021	S
15 Drospirenone; Estetrol (Nextstellis)	Mayne Pharma	Spirolactone and estrogen analog	Contraception	04/15/2021	S
16 Pegcetacoplan (Empaveli)	Apellis	Complement protein C3 inhibitor	Paroxysmal nocturnal hemoglobinuria (PNH)	05/14/2021	P, O
17 Piflufolastat F-18 (Pylarify)	Progenics	¹⁸ F labelled prostate-specific membrane antigen (PSMA) imaging agent	Prostate cancer imaging	05/26/2021	P
18 Olanzapine; Samidorphan L-malate (Lybalvi)	Alkermes	Atypical antipsychotic and opioid antagonist	Schizophrenia and bipolar I disorder	05/28/2021	S
19 Infigratinib phosphate (Truseltiq)	Helsinn Hlthcare	FGFR1-3 inhibitor	Advanced cholangiocarcinoma with <i>FGFR2</i> fusions/rearrangements	05/28/2021	P, O
20 Sotorasib (Lumakras)	Amgen	KRAS ^{G12C} inhibitor	KRAS ^{G12C} -mutated NSCLC	05/28/2021	P, O
21 Ibrexafungerp citrate (Brexafemme)	Scynexis	Triterpenoid antifungal	Vulvovaginal candidiasis	06/01/2021	P
22 Finerenone (Kerendia)	Bayer	Non-steroidal mineralocorticoid receptor (MR) antagonist	Chronic kidney disease (CKD) with type 2 diabetes	07/09/2021	P
23 Fexinidazole (Fexinidazole)	Sanofi	Nitroimidazole antimicrobial	Sleeping sickness	07/16/2021	P, O
24 Belumosudil mesylate (Rezurock)	Kadmon	Rho-associated coiled-coil-containing protein kinase 2 (ROCK2) kinase inhibitor	Chronic graft-versus-host disease (GVHD)	07/16/2021	P, O
25 Odevixibat (Bylvay)	Albireo	Ileal bile acid transporter (IBAT) inhibitor	Pruritus in progressive familial intrahepatic cholestasis (PFIC)	07/20/2021	P, O
26 Belzutifan (Welireg)	Merck & Co	Hypoxia-inducible factor 2α (HIF-2α) inhibitor	von Hippel-Lindau (VHL) disease	08/13/2021	P, O
27 Difelikefalin (Korsuva)	Cara Therap	κ-Opioid receptor agonist	Pruritus associated with chronic kidney disease (CKD)	08/23/2021	P
28 Mobocertinib succinate (Exkivity)	Takeda	EGFR kinase inhibitor	EGFR exon 20-mutated NSCLC	09/15/2021	P, O
29 Atogepant (Qulipta)	AbbVie	Calcitonin gene-related peptide (CGRP) receptor antagonist	Episodic migraine	09/28/2021	S
30 Maralixibat chloride (Livmarli)	Mirum	Ileal bile acid transporter (IBAT) inhibitor	Pruritus in Alagille syndrome	09/29/2021	P, O
31 Avacopan (Tavneos)	ChemoCentryx	Complement 5a receptor antagonist	Anti-neutrophil cytoplasmic (auto)antibody (ANCA)-associated vasculitis	10/07/2021	S, O
32 Asciminib HCl (Scemblix)	Novartis	ABL/BCR-ABL1 kinase inhibitor	Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML)	10/29/2021	P, O
33 Vosoritide (Voxzogo)	Biomarin	C-type natriuretic peptide (CNP) analog	Achondroplasia	11/19/2021	P, O
34 Maribavir (Livtency)	Takeda	Cytomegalovirus (CMV) pUL97 kinase inhibitor	Post-transplant CMV infection	11/23/2021	P, O
35 Pafolacianine sodium (Cytalux)	On Target Labs	Fluorescent folate receptor α (FRα) imaging agent	Ovarian cancer imaging	11/29/2021	P, O
36 Inclisiran sodium (Leqvio)	Novartis	Proprotein convertase subtilisin-kexin type 9 (PCSK9)-targeted siRNA	Heterozygous familial hypercholesterolemia (HeFH) or atherosclerotic cardiovascular disease (ASCVD)	12/22/2021	S
2021 Biologics license applications = 14					
1 Evinacumab (Evekeza)	Regeneron	Angiopoetin-like protein 3 (ANGPTL3)-directed mAb	Homozygous familial hypercholesterolemia (HoFH)	02/11/2021	P, O
2 Dostarlimab (Jemperli)	GlaxoSmithKline	PD1-directed mAb	Endometrial cancer	04/22/2021	P

Supplementary data: Table 1 – FDA-approved drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2021 Biologics license applications = 14					
3 Loncastximab tesirine (Zynlonta)	ADC Therapeutics	CD19-directed ADC	B-cell lymphoma	04/23/2021	P, O
4 Amivantamab (Rybrevant)	Janssen Biotech	EGFR- and MET-bispecific antibody	EGFR exon 20-mutated NSCLC	05/21/2021	P
5 Aducanumab (Aduhelm)	Biogen	Amyloid- β -directed mAb	Alzheimer's disease	06/07/2021	P
6 Asparaginase erwinia chrysanthemi (Rylaze)	Jazz	Recombinant asparagine-specific enzyme	Acute lymphoblastic leukaemia (ALL), and lymphoblastic lymphoma (LBL), in patients allergic to <i>E. coli</i> -derived products	06/30/2021	S, O
7 Anifrolumab (Saphnelo)	AstraZeneca	Type 1 interferon receptor (IFNAR)-targeted mAb	Systemic lupus erythematosus (SLE)	07/30/2021	S
8 Avalglucosidase alfa (Nexviazyme)	Genzyme	Recombinant α -glucosidase	Pompe disease	08/06/2021	P, O
9 Lonapegsomatropin (Skytrofa)	Ascendis Pharma	PEGylated human growth hormone	Growth failure due to growth hormone deficiency (GHD)	08/25/2021	S, O
10 Tisotumab vedotin (Tivdak)	Seagen	Tissue-factor-targeted ADC	Cervical cancer	09/20/2021	P, O
11 Ropeginterferon alfa-2b (Besremi)	PharmaEssentia	PEGylated interferon α -2b	Polycythemia vera	11/12/2021	S, O
12 Efgartigimod alfa (Vyvgart)	Argenx	Neonatal Fc receptor (FcRn)-binding Fc fragment	Myasthenia gravis	12/17/2021	S, O
13 Tezepelumab (Tezspire)	AstraZeneca	Thymic stromal lymphopoietin (TSLP)-directed mAb	Severe asthma	12/17/2021	P
14 Tralokinumab (Adbry)	LEO Pharma	LEO Pharma Interleukin-13 (IL-13)-directed mAb	Atopic dermatitis	12/27/2021	S

Supplementary data: Table 2 – FDA-approved cancer drugs

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
1991 New molecular entities = 5					
1 Ondansetron HCl (Zofran)	Novartis	5-HT ₃ receptor antagonist	Nausea and vomiting caused by radiotherapy, anesthesia, surgery or cytotoxic chemotherapy drugs	01/04/1991	P
2 Gallium nitrate (Ganite)	Chapter 7 Trustee	Bone-resorption inhibitor	Hypercalcemia of malignancy	01/17/1991	P, O
3 Fludarabine phosphate (Fludara)	Genzyme Corp	DNA synthesis inhibitor	B-cell chronic lymphocytic leukemia	04/18/1991	P
4 Pentostatin (Nipent)	Hospira	Purine analog, irreversible inhibitor of adenosine deaminase	INF α -refractory hairy cell leukemia	10/11/1991	P, O
5 Pamidronate disodium (Aredia)	Novartis	Bone-resorption inhibitor	Hypercalcemia of malignancy	10/31/1991	P
1991 Biologics license applications = 2					
1 Filgrastim (Neupogen)	Amgen	Recombinant human granulocyte colony-stimulating factor (G-CSF)	Severe neutropenia in patients with non-myeloid malignancies	02/20/1991	N/A
2 Sargramostim (Leukine)	Berlex Labs	Recombinant human granulocyte macrophage colony-stimulating factor (GM-CSF)	Myeloid reconstitution after PBPC/bone marrow transplantation, or with NHL, ALL, HL	03/05/1991	O
1992 New molecular entities = 2					
1 Teniposide (Vumon)	HQ spcIt Pharma	Topoisomerase II inhibitor	Refractory childhood acute lymphoblastic leukemia	07/14/1992	P, O
2 Paclitaxel (Taxol)	HQ SpcIt Pharma	Microtubule-stabilizing agent	Advanced ovarian cancer	12/29/1992	P, O
1992 Biologics license applications = 2					
1 Aldesleukin (Proleukin)	Chiron	Recombinant human interleukin-2	Metastatic renal cell carcinoma	05/05/1992	O
2 Indium In-111 satumomab pentetide (OncoScint)	Cytogen	TAG-72-specific radiolabeled mAb	Imaging of colorectal or ovarian cancer	12/29/1992	O
1993 New molecular entities = 3					
1 Cladribine (Leustatin)	Janssen Pharms	Adenosine deaminase inhibitor	Hairy cell leukemia and multiple sclerosis	02/26/1993	S
2 Strontium chloride Sr-89 (Metastron)	Q Biomed	A radiopharmaceutical that concentrates in the bone of invaded tumor	Bone metastasis of tumor induced pain	06/18/1993	P
3 Granisetron HCl (Kytrel)	Roche	5-HT ₃ receptor agonist	Chemotherapy-induced nausea	12/29/1993	S
1994 New molecular entities = 4					
1 Iobenguane sulfate I-131	Pharmalucence	Radiopharmaceutical	Location of pheochromocytomas and neuroblastomas	03/25/1994	P
2 Indium In-111 pentetreotide kit (Octreoscan)	Curium	Radioactive diagnostic agent	Location of metastatic neuroblastomas	06/02/1994	P
3 Technetium Tc-99m bicasate kit (Neurolite)	Lantheus Medcl	Radioactive diagnostic agent	Localization of neuroendocrine tumors bearing somatostatin receptors	11/23/1994	S
4 Vinorelbine tartrate (Navelbine)	Pierre Fabre	Microtubule-destabilizing agent	Non-small-cell lung cancer (NSCLC)	12/23/1994	P
1994 Biologics license applications = 1					
1 Pegaspargase (Oncaspar)	Sigma Tau	<i>Escherichia coli</i> -derived L-asparaginase	Pediatric acute lymphoblastic leukaemia	02/01/1994	O
1995 New molecular entities = 5					
1 Dexrazoxane HCl (Zincard)	Pfizer	DNA topoisomerase II inhibitor and iron ions chelator	Doxorubicin-caused cardiomyopathy in patients with breast cancer	05/26/1995	P, O
2 Bicalutamide (Casodex)	Ani Pharms	Androgen receptor antagonist	Advanced prostate cancer	10/04/1995	S
3 Amifostine (Ethyol)	Clinigen	Binds to and detoxifies cytotoxic platinum-containing metabolites of cisplatin	Cisplatin caused cumulative renal toxicity in patients with ovarian cancer	12/08/1995	P, O
4 Porfimer sodium (Photofrin)	Pinnacle Biologs	A photosensitizer used for photodynamic therapy	Advanced esophageal cancer	12/27/1995	P, O
5 Anastrozole (Arimidex)	Ani Pharms	Aromatase inhibitor	Advanced breast cancer in post-menopausal women	12/27/1995	S

Supplementary data: Table 2 – FDA-approved cancer drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
1996 New molecular entities = 5					
1 Docetaxel (Taxotere)	Sanofi	Microtubule-stabilizing agent	Locally advanced or metastatic breast cancer	05/14/1996	P
2 Gemcitabine HCl (Gemzar)	Eli Lilly	DNA synthesis inhibitor	Locally advanced or metastatic pancreatic cancer	05/15/1996	P
3 Topotecan HCl (Hycamtin)	Novartis	DNA topoisomerases inhibitor	Relapsed small cell lung cancer	05/28/1996	P
4 Irinotecan HCl (Camptosar)	Pfizer	Topoisomerase I inhibitor	Metastatic colorectal cancer	06/14/1996	P
5 Nilutamide (Nilandron)	Concordia	Androgen receptor antagonist	Metastatic prostate cancer	09/19/1996	S
1996 Biologics license applications = 3					
1 Arcitumomab (CEA-Scan)	Immunomedics	^{99m} Tc labelled anti-CEA mouse IgG1 (Fab)	Recurrent colorectal cancer imaging	06/28/1996	O
2 Nofetumomab merpentan (Verluma)	Boehringer Ingelheim	^{99m} Tc labelled anti-EpCAM (and/or CD20/MS4A1) mouse IgG2b (Fab)	Small cell lung cancer imaging	8/20/1996	N/A
3 Capromab pendetide (Prostascint)	Cytogen	¹¹¹ In labelled anti-PSMA mouse mAb	Diagnosis of metastatic prostate cancer	10/28/1996	N/A
1997 New molecular entities = 6					
1 Anagrelide HCl (Agrylin)	Takeda	Phosphodiesterase 3 (PDE3) and phospholipase A2 (PLA2) inhibitor	Thrombocytopenia, secondary to myeloproliferative neoplasms	12/06/1996	S
2 Samarium Sm-153 lexidronam pentasodium (Quadramet)	Lantheus Medical	¹⁵³ Sm labelled Radiopharmaceutical, chelator moiety associates with hydroxyapatite crystals concentrated in areas of bone turnover	Bone metastasis of tumor induced pain	03/28/1997	S
3 Toremifene citrate (Fareston)	Kyowa kirin	Estrogen receptor (ER) inhibitor	ER-positive metastatic breast cancer	05/29/1997	S, O
4 Letrozole (Femara)	Novartis	Aromatase inhibitor	Advanced breast cancer	07/25/1997	S
5 Dolasetron mesylate (Anzemet)	Validus Pharms	5-HT ₃ receptor antagonist	Chemotherapy-induced nausea and vomiting	09/11/1997	S
6 Mangafodipir trisodium (Teslascan)	IC Targets	MRI contrast agent	Imaging of liver lesions with suspected metastatic disease or hepatocellular carcinomas	11/26/1997	S
1997 Biologics license applications = 2					
1 Oprelvekin (Neumega)	Genetics institute	Recombinant human interleukin-11 (IL-11)	Chemotherapy-induced thrombocytopenia	11/25/1997	N/A
2 Rituximab (Rituxan)	Genentech	CD20-directed mAb	B-cell non-Hodgkin's lymphoma	11/26/1997	O
1998 New molecular entities = 2					
1 Capecitabine (Xeloda)	Roche	Prodrug of 5-FU	Metastatic breast cancer	04/30/1998	P
2 Valrubicin (Valstar)	Endo Pharm	A semisynthetic analog of anthracycline doxorubicin	BCG-refractory CIS of urinary bladder cancer	09/25/1998	P, O
1998 Biologics license applications = 2					
1 Trastuzumab (Herceptin)	Genentech	HER2-directed mAb	HER2-positive breast cancer	09/25/1998	P
2 Thyrotropin alfa (Thyrogen)	Genzyme	Recombinant human thyroid stimulating hormone	Diagnostic testing for thyroid tissue remnants following radioiodine ablation, and alongside radioactive agents to destroy thyroid tissue	11/30/1998	O
1999 New molecular entities = 6					
1 Alitretinoin (Panretin)	Concordia	9-cis-retinoic acid, a form of vitamin A	AIDS-related Kaposi's sarcoma	02/02/1999	P, O
2 Technetium Tc-99m depreotide (Neo tect kit)	Cis Bio Intl	^{99m} Tc labelled radioactive diagnostic agent	Imaging of malignant lung tumors in patients with highly suspect for malignancy	08/03/1999	P
3 Temozolomide (Temodar)	Merck & Co	DNA alkylating agent	Glioblastoma	08/11/1999	P, O
4 Epirubicin HCl (Ellence)	Pfizer	DNA topoisomerase II inhibitor	Primary breast cancer with axillary node tumor involvement	09/15/1999	P, O
5 Exemestane (Aromasin)	Pfizer	Aromatase inhibitor	ER-positive early breast cancer	10/21/1999	S, O
6 Bexarotene (Targretin)	Valeant Luxembourg	Retinoid, ligand of retinoid X receptors (RXRs)	Cutaneous T-cell lymphoma	12/29/1999	P, O
1999 Biologics license applications = 1					
1 Denileukin difitox (Ontak)	Eisai	Fusion protein consisting of diphtheria toxin fragments and interleukin-2	Cutaneous T-cell lymphoma	02/05/1999	O

Supplementary data: Table 2 – FDA-approved cancer drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2000 New molecular entities = 2					
1 Triptorelin pamoate (Trelstar)	Verity	GnRH agonist	Advanced prostate cancer	06/15/2000	S
2 Arsenic trioxide (Trisenox)	Cephalon	Degradation of PML-RAR α fusion protein	Acute promyelocytic leukemia characterized by the presence of the t (15; 17) translocation or PML/RAR α gene expression	09/25/2000	P, O
2000 Biologics license applications = 1					
1 Gemtuzumab ozogamicin (Mylotarg)	Wyeth Pharms	CD33-directed antibody-drug conjugate (ADC)	Relapsed or refractory CD33-positive acute myeloid leukemia (AML)	05/17/2000	O

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2001 New molecular entities = 2					
1 Imatinib mesylate (Gleevec)	Novartis	Tyrosine kinase inhibitor	Chronic myeloid leukemia	05/10/2001	P
2 Zoledronic acid (Zometa)	Novartis	Bone-resorption inhibitor	Hypercalcemia of malignancy	08/20/2001	P, O
2001 Biologics license applications = 1					
1 Alemtuzumab (Campath)	Genzyme	CD52-directed mAb	B-cell chronic lymphocytic leukemia	05/07/2001	O

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2002 New molecular entities = 2					
1 Fulvestrant (Faslodex)	AstraZeneca	Estrogen receptor antagonist	HR-positive metastatic breast cancer	04/25/2002	S
2 Oxaliplatin (Eloxatin)	Sanofi	Organoplatinum alkylating agent, increases tumor response rate to chemotherapy	Colorectal cancer (in combination with 5-fluorouracil and leucovorin)	08/09/2002	P
2002 Biologics license applications = 2					
1 Pegfilgrastim (Neulasta)	Amgen	PEGylated form of recombinant human granulocyte colony-stimulating factor (G-CSF)	Febrile neutropenia or myelosuppressive chemotherapy-induced neutropenia	01/31/2002	N/A
2 Ibritumomab tiuxetan (Zevalin)	IDEC Pharms	¹¹¹ In and ⁹⁰ Y labelled CD20-specific radiotherapeutic mAb	B-cell non-Hodgkin's lymphoma	02/19/2002	O

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2003 New molecular entities = 5					
1 Aprepitant (Eemend)	Merck & Co	NK1 receptor antagonist	Chemotherapy-induced nausea	03/26/2003	P
2 Gefitinib (Iressa)	AstraZeneca	EGFR kinase inhibitor	Non-small-cell lung cancer (NSCLC)	05/05/2003	P
3 Bortezomib (Velcade)	Takeda Pharms	Proteasome inhibitor	Multiple myeloma	05/13/2003	P, O
4 Palonosetron HCl (Aloxi)	Helsinn	5-HT ₃ receptor antagonist	Chemotherapy-induced nausea	07/25/2003	S
5 Abarelix (Plenaxis)	Speciality European	GnRH receptor antagonist	Advanced prostate cancer	11/25/2003	P
2003 Biologics license applications = 1					
1 Tositumomab and iodine I-131 tositumomab (Bexxar)	Corixa	CD20-directed radiotherapeutic mAb	Non-Hodgkin's lymphoma	06/30/2003	P, O

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2004 New molecular entities = 3					
1 Pemetrexed disodium (Alimta)	Eli Lilly	Folate analog	Malignant pleural mesothelioma	02/04/2004	P, O
2 Erlotinib HCl (Tarceva)	OSI Pharms	EGFR inhibitor	Non-small-cell lung cancer (NSCLC)	11/18/2004	P
3 Clofarabine (Clolar)	Genzyme	Nucleoside antimetabolite, DNA synthesis inhibitor	Relapsed or refractory acute lymphoblastic leukemia	12/28/2004	P, O
2004 Biologics license applications = 3					
1 Cetuximab (Erbix)	ImClone	EGFR-directed mAb	Colorectal cancer	02/12/2004	N/A
2 Bevacizumab (Avastin)	Genentech	VEGF-A-directed mAb	Colorectal cancer	02/26/2004	O
3 Palifermin (Kepivance)	Biovitrum	Recombinant human keratinocyte growth factor	Oral mucositis following radiation or chemotherapy	12/15/2004	N/A

Supplementary data: Table 2 – FDA-approved cancer drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2005 New molecular entities = 2					
1 Nelarabine (Arranon)	Novartis	Purine nucleoside analog, inhibits the DNA elongation	T-cell acute lymphoblastic leukaemia and T-cell lymphoblastic lymphoma	10/28/2005	P, O
2 Sorafenib tosylate (Nexavar)	Bayer	Multi-target TKI (VEGFR2/3, PDGFR β , FLT3, KIT, RAF1, and BRAF)	Advanced renal cell carcinoma	12/01/2005	P, O
2006 New molecular entities = 3					
1 Sunitinib malate (Sutent)	CPPI CV	Multi-target TKI (VEGFRs, PDGFR α/β , CSF1R, KIT, and FLT3)	Imatinib-resistant gastrointestinal stromal tumor and advanced renal cell carcinoma	01/26/2006	P
2 Dasatinib (Sprycel)	Bristol-Myers Squibb	Tyrosine kinase inhibitor	Chronic myeloid leukemia	06/28/2006	P, O
3 Vorinostat (Zolinza)	Merck & Co	Histone deacetylase inhibitor	Cutaneous T-cell lymphoma	10/06/2006	P, O
2006 Biologics license applications = 1					
1 Panitumumab (Vectibix)	Amgen	EGFR-directed mAb	EGFR-expressing metastatic colorectal carcinoma	09/27/2006	N/A
2007 New molecular entities = 4					
1 Lapatinib Ditosylate (Tykerb)	Novartis	HER2 and EGFR inhibitor	Advanced or metastatic breast cancer (HER2-positive)	03/13/2007	P
2 Temsirolimus (Torisel)	Merck & Co	Mammalian target of rapamycin (mTOR) inhibitor	Advanced renal cell carcinoma	05/30/2007	P, O
3 Ixabepilone (Ixempra)	R-Pharm US	Microtubule-stabilizing agent	Advanced or metastatic breast cancer	10/16/2007	P
4 Nilotinib HCl (Tasigna)	Novartis	BCR-ABL kinase inhibitor	Chronic myelogenous leukemia	10/29/2007	S, O
2008 New molecular entities = 5					
1 Fosaprepitant dimeglumine (Eemend)	Merck & Co	Prodrug of aprepitant, NK1 receptor antagonist	Nausea and vomiting caused by chemotherapy	01/25/2008	S
2 Bendamustine HCl (Treanda)	Cephalon	Mechlorethamine derivative with DNA-alkylating activity	Chronic lymphocytic leukemia	03/20/2008	P, O
3 Iobenguane sulfate I-123 (AdreView)	GE Healthcare	Taken up by the noradrenaline transporter in adrenergic nerve terminals	Radiopharmaceutical agent, detection of primary or metastatic pheochromocytoma or neuroblastoma	09/19/2008	P, O
4 Plerixafor (Mozobil)	Genzyme	CXCR4 antagonist	Autologous transplantation in patients with non-Hodgkin's lymphoma and multiple myeloma	12/15/2008	P, O
5 Degarelix acetate (Firmagon)	Ferring	GnRH receptor antagonist	Advanced prostate cancer	12/24/2008	S
2009 New molecular entities = 4					
1 Everolimus (Afinitor)	Novartis	Mammalian target of rapamycin (mTOR) inhibitor	Advanced renal cell carcinoma	03/30/2009	P
2 Pralatrexate (Folotyn)	Acrotech	Folate analogue metabolic inhibitor that competitively inhibits dihydrofolate reductase	Peripheral T cell lymphoma	09/24/2009	P, O
3 Pazopanib HCl (Votrient)	Novartis	Multi-target TKI (VEGFRs, PDGFR α/β , FGFR1/2, KIT)	Advanced renal cell carcinoma	10/19/2009	S
4 Romidepsin (Istodax)	Celgene	Histone deacetylase inhibitor	Cutaneous T-cell lymphoma	11/05/2009	S
2009 Biologics license applications = 1					
1 Ofatumumab (Arzerra)	Novartis	CD20-directed mAb	Chronic lymphocytic leukemia	10/26/2009	P, O
2010 New molecular entities = 2					
1 Cabazitaxel (Jevtana kit)	Sanofi	Microtubule-stabilizing agent	Prostate cancer	06/17/2010	P
2 Eribulin mesylate (Halaven)	Eisai	Microtubule-destabilizing agent	Breast cancer	11/15/2010	P

Supplementary data: Table 2 – FDA-approved cancer drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2011 New molecular entities = 4					
1 Vandetanib (Caprelsa)	Genzyme	Multi-target TKI (VEGFR2/3, EGFR, and RET)	Unresectable or metastatic medullary thyroid cancer	04/06/2011	P, O
2 Abiraterone acetate (Zytiga)	Janssen Biotech	CYP17A1 inhibitor	Metastatic castration-resistant prostate cancer	04/28/2011	P
3 Vemurafenib (Zelboraf)	Roche	BRAF inhibitor	BRAF-positive unresectable or metastatic melanoma	08/17/2011	P, O
4 Crizotinib (Xalkori)	Merck & Co	Multi-target TKI (ALK, ROS1, and MET)	ALK-positive advanced or metastatic NSCLC	08/26/2011	P, O
2011 Biologics license applications = 3					
1 Ipilimumab (Yervoy)	Bristol-Myers Squibb	Cytotoxic T-lymphocyte antigen 4 (CTLA-4)-directed mAb	Unresectable or metastatic melanoma	03/25/2011	P, O
2 Brentuximab vedotin (Adcetris)	Seattle Genetics	CD30-directed antibody drug conjugate (ADC)	Hodgkin's lymphoma; systemic anaplastic large cell lymphoma	08/19/2011	P, O
3 Asparaginase Erwinia chrysanthemi (Erwinaze)	EUSA Pharma (USA)	<i>Erwinia chrysanthemi</i> -derived L-asparaginase	Acute lymphoblastic leukemia	11/18/2011	P, O

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2012 New molecular entities = 9					
1 Axitinib (Inlyta)	Pfizer	VEGFRs inhibitor	Advanced renal cell carcinoma	01/27/2012	S
2 Vismodegib (Erivedge)	Genentech	Smoothed (Hedgehog pathway) inhibitor	Metastatic or locally advanced basal cell carcinoma	01/30/2012	P
3 Carfilzomib (Kyprolis)	Onyx Therap	20S proteasome inhibitor	Multiple myeloma	07/20/2012	S, O
4 Enzalutamide (Xtandi)	Astellas	Androgen receptor inhibitor	Metastatic castration-resistant prostate cancer	08/31/2012	P
5 Bosutinib monohydrate (Bosulif)	Pfizer	BCR-ABL inhibitor; SRC family kinase inhibitor	Chronic, accelerated or blast phase Ph+ chronic myelogenous leukemia	09/04/2012	S, O
6 Regorafenib (Stivarga)	Bayer	Multi-target TKI (RET, VEGFRs, KIT, PDGFRα/β, FGFR1/2, RAF1, BRAFWT, and BRAFV600E)	Metastatic colorectal cancer	09/27/2012	P
7 Omacetaxine mepesuccinate (Synribo)	Teva	Cephalotaxine, inhibits protein chain elongation by binding the large ribosomal subunit	Chronic or accelerated-phase chronic myeloid leukemia	10/26/2012	S, O
8 Cabozantinib S-malate (Cometriq)	Exelixis	Multi-target TKI (VEGFRs, MET, RET, FLT3, KIT, TIE2, and AXL)	Progressive, metastatic medullary thyroid cancer	11/29/2012	P, O
9 Ponatinib HCl (Iclusig)	Takeda	Multi-kinase inhibitor (BCR-ABL, KIT, RET and FLT3)	Chronic, accelerated or blast-phase chronic myeloid leukemia	12/14/2012	P, O
2012 Biologics license applications = 3					
1 Pertuzumab (Perjeta)	Genentech	HER2-directed mAb	HER2-positive metastatic breast cancer	06/08/2012	P
2 Ziv-aflibercept (Zaltrap)	Sanofi	Soluble receptor decoy that binds VEGF-A, VEGF-B, and PlGF	Metastatic colorectal cancer	08/03/2012	P
3 Tbo-Filgrastim (Neutroval)	Sicor Biotech	Methionyl human G-CSF	Severe neutropaenia in patients with non-myeloid malignancies	08/29/2012	S

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2013 New molecular entities = 7					
1 Pomalidomide (Pomalyst)	Celgene	Thalidomide analog, immunomodulatory antineoplastic agent	Multiple myeloma	02/08/2013	S, O
2 Technetium TC 99m tilmanocept (Lymphoseek kit)	Cardinal Health 414	^{99m} Tc labelled radioactive diagnostic agent	Lymphatic mapping in patients with breast cancer or melanoma	03/13/2013	S
3 Radium Ra-223 dichloride (Xofigo)	Bayer	α-particle-emitting radioactive therapeutic	Castration-resistant prostate cancer	05/15/2013	P
4 Dabrafenib mesylate (Tafinlar)	Novartis	Kinase inhibitor with activity against BRAFV600E/D/K, wild-type BRAF and other kinases	Unresectable or metastatic melanoma with BRAFV600E mutation	05/29/2013	S, O
5 Trametinib dimethyl sulfoxide (Mekinist)	Novartis	MEK1 and MEK2 kinase inhibitor	Unresectable or metastatic melanoma with BRAFV600E mutation	05/29/2013	S, O
6 Afatinib dimaleate (Gilotrif)	Boehringer Ingelheim	EGFR, HER2, and HER4 inhibitor	Metastatic NSCLC with EGFR exon 19 deletions or exon 21 (L858R) substitution mutations	07/12/2013	P, O
7 Ibrutinib (Imbruvica)	Pharmacyclics	Bruton's tyrosine kinase inhibitor	Mantle cell lymphoma	11/13/2013	P, O
2013 Biologics license applications = 2					
1 Adu-trastuzumab emtansine (Kadcyla)	Genentech	HER2-directed ADC	HER2-positive metastatic breast cancer	02/22/2013	P
2 Obinutuzumab (Gazyva)	Genentech	CD20-directed mAb	Previously untreated chronic lymphocytic leukemia	11/01/2013	P, O

Supplementary data: Table 2 – FDA-approved cancer drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2014 New molecular entities = 5					
1 Ceritinib (Zykadia)	Novartis	Multi-target TKI (ALK, IGF1R, INSR, and ROS1)	ALK-positive metastatic NSCLC	04/29/2014	P, O
2 Belinostat (Beleodaq)	Acrotech	Histone-deacetylase inhibitor	Peripheral T-cell lymphoma	07/03/2014	P, O
3 Idelalisib (Zydelig)	Gilead Sciences	PI3Kδ inhibitor	Chronic lymphocytic leukaemia (CLL), B-cell non-Hodgkin's lymphoma, and small lymphocytic lymphoma (SLL)	07/23/2014	P, O
4 Netupitant; Palonosetron HCl (Akinzo)	Helsinn Hlthcare	NK1-receptor antagonist plus 5-HT ₃ receptor antagonist	Chemotherapy-related nausea	10/10/2014	S
5 Olaparib (Lynparza)	AstraZeneca	PARP inhibitor	Advanced BRCA-mutated ovarian cancer	12/19/2014	P, O
2014 Biologics license applications = 4					
1 Ramucirumab (Cyramza)	Eli Lilly & Co	VEGFR2-directed mAb	Gastric cancer	04/21/2014	P, O
2 Pembrolizumab (Keytruda)	Merck & Co	PD1-directed mAb	Metastatic melanoma	09/04/2014	P, O
3 Blinatumomab (Blincyto)	Amgen	CD19- and CD3-bispecific mAb	B-cell precursor acute lymphoblastic leukemia (ALL)	12/03/2014	P, O
4 Nivolumab (Opdivo)	Bristol-Myers Squibb	PD1-directed mAb	Unresectable or metastatic melanoma	12/22/2014	P, O
2015 New molecular entities = 11					
1 Palbociclib (Ibrance)	Pfizer	Cyclin-dependent kinase 4/6 (CDK4/6) inhibitor	HER2-negative and HR-positive advanced or metastatic breast cancer	02/03/2015	P
2 Lenvatinib mesylate (Lenvima)	Eisai	Multi-target TKI (VEGFRs, FGFRs, PDGFRα, RET, and KIT)	Thyroid cancer	02/13/2015	P, O
3 Panobinostat lactate (Farydak)	Secura	Histone deacetylase inhibitor	Multiple myeloma	02/23/2015	P, O
4 Sonidegib phosphate (Odomzo)	Sun Pharma Global	Smoothed inhibitor	Basal cell carcinoma	07/24/2015	S
5 Rolapitant HCl (Varubi)	Tersera	Neurokinin 1 receptor antagonist	Nausea and vomiting associated with chemotherapy	09/01/2015	S
6 Tipiracil HCl; Trifluridine (Lonsurf)	Taiho Oncology	Thymidine phosphorylase inhibitor plus a nucleoside metabolic inhibitor	Colorectal cancer	09/22/2015	S
7 Trabectedin (Yondelis)	Janssen Prods	Alkylating drug, interacts with the minor groove of DNA	Liposarcoma or leiomyosarcoma	10/23/2015	P, O
8 Cobimetinib fumarate (Cotellic)	Genentech	MEK inhibitor	Melanoma with BRAF ^{V600E/K} mutations	11/10/2015	P, O
9 Osimertinib mesylate (Tagrisso)	AstraZeneca	EGFR inhibitor	NSCLC with EGFR ^{T790M} mutations	11/13/2015	P, O
10 Ixazomib citrate (Ninlaro)	Takeda	Oral proteasome inhibitor	Multiple myeloma	11/20/2015	P, O
11 Alectinib HCl (Alecensa)	Roche	ALK inhibitor	Non-small-cell lung cancer (NSCLC)	12/11/2015	P, O
2015 Biologics license applications = 4					
1 Dinutuximab (Unituxin)	United Therap	GD2-directed mAb	High-risk neuroblastoma	03/10/2015	P, O
2 Daratumumab (Darzalex)	Janssen Biotech	CD38-directed mAb	Multiple myeloma	11/16/2015	P, O
3 Necitumumab (Portrazza)	Eli Lilly & Co	EGFR-directed mAb	Non-small-cell lung cancer (NSCLC)	11/24/2015	S, O
4 Elotuzumab (Empliciti)	Bristol-Myers Squibb	SLAMF7-directed mAb	Multiple myeloma	11/30/2015	P, O
2016 New molecular entities = 4					
1 Venetoclax (Venclexta)	AbbVie	BCL-2 inhibitor	Chronic lymphocytic leukemia	04/11/2016	P, O
2 Fluciclovine F-18 (Axumin)	Blue Earth	¹⁸ F labelled radioactive diagnostic agent	Imaging diagnosis of suspected prostate cancer recurrence	05/27/2016	P
3 Gallium dotatate Ga-68 (Netspot)	AAA USA Inc	⁶⁸ Ga labelled radioactive diagnostic	Imaging diagnosis of neuroendocrine tumors	06/01/2016	P, O
4 Rucaparib camsylate (Rubraca)	Clovis Oncology	PARP inhibitor	BRCA-positive ovarian cancer	12/19/2016	P, O
2016 Biologics license applications = 2					
1 Atezolizumab (Tecentriq)	Genentech	PDL1-directed mAb	Advanced or metastatic urothelial carcinoma	05/18/2016	P
2 Olaratumab (Lartruvo)	Eli Lilly & Co	PDGFRα-directed mAb	Soft tissue sarcoma	10/19/2016	P, O

Supplementary data: Table 2 – FDA-approved cancer drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2017 New molecular entities = 9					
1 Ribociclib succinate (Kisqali)	Novartis	CDK4/6 inhibitor	HR-positive, HER2-negative breast cancer	03/13/2017	P
2 Niraparib tosylate (Zejula)	GlaxoSmithKline	Poly-ADP ribose polymerase (PARP) inhibitor	Epithelial ovarian, fallopian tube or primary peritoneal cancer	03/27/2017	P, O
3 Brigatinib (Alunbrig)	Takeda	Multi-target TKI (ALK, EGFR, IGF1R, FLT3, and ROS1)	ALK-positive NSCLC	04/28/2017	P, O
4 Midostaurin (Rydapt)	Novartis	Fms-like tyrosine kinase 3 (FLT3) inhibitor	FLT3-positive acute myeloid leukemia (AML)	04/28/2017	P, O
5 Neratinib maleate (Nerlynx)	Puma Biotech	EGFR, HER2, and HER4 inhibitor	HER2-overexpressed breast cancer	07/17/2017	S
6 Enasidenib mesylate (Idhifa)	Celgene Corp	IDH2 inhibitor	IDH2-mutated acute myeloid leukemia (AML)	08/01/2017	P, O
7 Copanlisib 2HCl (Aliqopa)	Bayer	PI3K α / δ inhibitor	Follicular lymphoma (FL)	09/14/2017	P, O
8 Abemaciclib (Verzenio)	Eli Lilly & Co	CDK4/6 inhibitor	HR-positive, HER2-negative breast cancer	09/28/2017	P
9 Acalabrutinib (Calquence)	AstraZeneca	BTK inhibitor	Mantle cell lymphoma	10/31/2017	P, O
2017 Biologics license applications = 3					
1 Avelumab (Bavencio)	Emd Serono	PDL1-directed mAb	Merkel cell carcinoma	03/23/2017	P, O
2 Durvalumab (Imfinzi)	AstraZeneca	PDL1-directed mAb	Urothelial carcinoma	05/01/2017	P
3 Inotuzumab ozogamicin (Besponsa)	Wyeth Pharms	CD22-directed ADC	B cell precursor acute lymphoblastic leukemia (ALL)	08/17/2017	P, O
2018 New molecular entities = 13					
1 Lutetium dotatate Lu-177 (Lutathera)	AAA USA Inc	Somatostatin receptor-targeted radiopharmaceutical	Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)	01/26/2018	P, O
2 Apalutamide (Erleada)	Janssen Biotech	Androgen receptor inhibitor	Prostate cancer	02/14/2018	P
3 Fosnetupitant chloride HCl; Palonosetron HCl (Akyzreo IV)	Helsinn Group	Neurokinin 1 (NK1) receptor antagonist plus 5-HT ₃ receptor antagonist	Chemotherapy-induced nausea	04/19/2018	S
4 Encorafenib (Braftovi)	Array BioPharma	BRAF inhibitor	BRAF-mutated melanoma	06/27/2018	S, O
5 Binimetinib (Mektovi)	Array BioPharma	MEK inhibitor	BRAF-mutated melanoma	06/27/2018	S, O
6 Ivosidenib (Tibsovo)	Servier	Isocitrate dehydrogenase-1 (IDH1) inhibitor	IDH1-mutated acute myeloid leukemia (AML)	07/20/2018	P, O
7 Duvelisib (Copiktra)	Secura	Phosphatidylinositol 3-kinase δ / γ (PI3K δ / γ) inhibitor	Chronic lymphocytic leukaemia (CLL), follicular lymphoma (FL), and small lymphocytic lymphoma (SLL)	09/24/2018	P, O
8 Dacomitinib (Vizimpro)	Pfizer	EGFR inhibitor	EGFR-mutated NSCLC	09/27/2018	P, O
9 Talazoparib tosylate (Talzenna)	Pfizer	Poly-ADP ribose polymerase (PARP) inhibitor	BRCA-mutated HER2-negative breast cancer	10/16/2018	P
10 Lorlatinib (Lorbrena)	Pfizer	Multi-target TKI (ALK and ROS1)	ALK-positive NSCLC	11/02/2018	P, O
11 Glasdegib maleate (Daurismo)	Pfizer	Smoothened (Hedgehog pathway) inhibitor	Acute myeloid leukemia (AML)	11/21/2018	P, O
12 Larotrectinib sulfatate (Vitrakvi)	Bayer	TRKs inhibitor	NTRK-positive solid cancers	11/26/2018	P, O
13 Gilteritinib fumarate (Xospata)	Astellas	Fms-like tyrosine kinase 3 (FLT3) inhibitor	FLT3-positive AML	11/28/2018	P, O
2018 Biologics license applications = 4					
1 Moxetumomab pasudotox (Lumoxiti)	Innate Pharma	CD22-directed ADC	Hairy cell leukemia	09/13/2018	P, O
2 Cemiplimab (Libtayo)	Regeneron Pharmaceuticals	Programmed death receptor-1 (PD1)-directed mAb	Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)	09/28/2018	P
3 Calaspargase pegol (Asparlas)	Servier Pharma	Asparagine specific enzyme	Acute lymphoblastic leukemia (ALL)	12/20/2018	S, O
4 Tagraxofusp (Elzonris)	Stemline Therapeutics	IL-3 and diphtheria toxin fusion protein	Blastic plasmacytoid dendritic cell neoplasm	12/21/2018	P, O

Supplementary data: Table 2 – FDA-approved cancer drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2019 New molecular entities = 8					
1 Erdafitinib (Balversa)	Janssen Biotech	Fibroblast growth factor receptor (FGFR) inhibitor	Bladder cancer	04/12/2019	P
2 Alpelisib (Piqray)	Novartis	Phosphatidylinositol 3-kinase α (PI3K α) inhibitor	Breast cancer	05/24/2019	P
3 Selinexor (Xpovio)	Karyopharm Theraps	Exportin 1 (XPO1) inhibitor	Multiple myeloma	07/03/2019	P, O
4 Darolutamide (Nubeqa)	Bayer	Androgen receptor inhibitor	Prostate cancer	07/30/2019	P
5 Pexidartinib HCl (Turalio)	Daiichi Sankyo	CSF1R, KIT, and FLT3 inhibitor	Tenosynovial giant cell tumor	08/02/2019	P, O
6 Entrectinib (Rozytrek)	Genentech	Multi-target TKI (TRKs, ROS1, and ALK)	NTRK fusion- positive solid tumors and ROS1- positive NSCLC	08/15/2019	P, O
7 Gallium dotatoc Ga-68	UIHC PET Imaging	⁶⁸ Ga labelled radioactive diagnostic agent	Localization of somatostatin receptor-positive neuroendocrine tumors	08/21/2019	S, O
8 Zanubrutinib (Brukinsa)	BeiGene	Bruton's tyrosine kinase (BTK) inhibitor	Mantle cell lymphoma	11/14/2019	P, O
2019 Biologics license applications = 3					
1 Polatuzumab vedotin (Polivy)	Genentech	CD79b-directed antibody-drug conjugate (ADC)	Diffuse large B-cell lymphoma	06/10/2019	P, O
2 Enfortumab vedotin (Padcev)	Astellas	Nectin-4-directed antibody-drug conjugate (ADC)	Urothelial carcinoma	12/18/2019	P
3 Trastuzumab deruxtecan (Enhertu)	Daiichi Sankyo	HER2-directed antibody-drug conjugate (ADC)	HER2-positive breast cancer	12/20/2019	P
2020 New molecular entities = 13					
1 Avapritinib (Ayvakit)	Blueprint Medicines	PDGFR α , PDGFR α mutants, and KIT inhibitor	Gastrointestinal stromal tumor (GIST) with <i>PDGFRα</i> exon 18 mutations	01/09/2020	P, O
2 Tazemetostat (Tazverik)	Epizyme Inc	Enhancer of Zeste Homolog 2 (EZH2) inhibitor	Epithelioid sarcoma	01/23/2020	P, O
3 Tucatinib (Tukysa)	Seagen	HER2 inhibitor	HER2-positive breast cancer	04/17/2020	P, O
4 Pemigatinib (Pemazyre)	Incyte	Fibroblast growth factor receptor 1-3 (FGFR1-3) kinase inhibitor	Advanced cholangiocarcinoma with <i>FGFR2</i> fusions/rearrangements	04/17/2020	P, O
5 Capmatinib HCl (Tabrecta)	Novartis	MET kinase inhibitor	Non-small-cell lung cancer (NSCLC)	05/06/2020	P, O
6 Selpercatinib (Retevmo)	Loxo Oncology	RET kinase inhibitor	RET fusion-positive NSCLC and thyroid cancer	05/08/2020	P, O
7 Ripretinib (Qinlock)	Deciphera	PDGFR α , PDGFR α mutants, and KIT inhibitor	Advanced gastrointestinal stromal tumor (GIST)	05/15/2020	P, O
8 Fluoroestradiol F-18 (Cerianna)	Zionexa	¹⁸ F labelled radioactive diagnostic agent	Imaging, breast cancer	05/20/2020	S
9 Lurbinectedin (Zepzelca)	Jazz	DNA alkylating drug	Small-cell lung cancer	06/15/2020	P, O
10 Copper dotatate Cu-64 (Detectnet)	Radiomedix	⁶⁴ Cu labelled somatostatin analog	Imaging, cancer	09/03/2020	P, O
11 Pralsetinib (Gavreto)	Genentech	RET kinase inhibitor	RET fusion-positive NSCLC	09/04/2020	P, O
12 PSMA-11 Ga-68	UCLA	⁶⁸ Ga labelled radioactive diagnostic agent	Imaging, prostate cancer	12/01/2020	S
13 Relugolix (Orgovyx)	Myovant Sciences	GnRH receptor antagonist	Prostate cancer	12/18/2020	P
2020 Biologics license applications = 6					
1 Isatuximab (Sarclisa)	Sanofi	CD38-directed mAb	Multiple myeloma	03/02/2020	S, O
2 Sacituzumab govitecan (Trodelvy)	Immunomedics Inc	Trophoblast cell surface antigen 2 (Trop2)-directed ADC	Triple-negative breast cancer	04/22/2020	P
3 Tafasitamab (Monjuvi)	MorphoSys	CD19-directed mAb	Diffuse large B-cell lymphoma (DLBCL)	07/31/2020	P, O
4 Belantamab mafodotin (Blenrep)	GlaxoSmithKline	B-cell maturation antigen (BCMA)-directed ADC	Multiple myeloma	08/05/2020	P, O
5 Naxitamab (Danyelza)	Y-mAbs Therapeutics	GD2-directed mAb	High-risk neuroblastoma	11/25/2020	P, O
6 Margetuximab (Margenza)	MacroGenics	HER2-directed mAb	HER2-positive breast cancer	12/16/2020	S

Supplementary data: Table 2 – FDA-approved cancer drugs (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
2021 New molecular entities = 11					
1 Tepotinib HCl (Tepmetko)	Emd Serono	MET kinase inhibitor	Non-small-cell lung cancer (NSCLC)	02/03/2021	P, O
2 Ubralisib tosylate (Ukoniq)	TG Theraps	PI3Kδ and CK1ε inhibitor	Relapsed or refractory marginal zone lymphoma (MZL), follicular lymphoma	02/05/2021	P, O
3 Trilaciclib 2HCl (Cosela)	G1 Therap	CDK4/6 kinase inhibitor	Chemotherapy-induced myelosuppression	02/12/2021	P
4 Melphalan flufenamide HCl (Pepaxto)	Oncopeptides	Peptide-conjugated alkylating drug	Multiple myeloma	02/26/2021	P, O
5 Tivozanib HCl (Fotivda)	Aveo Pharms	VEGFRs inhibitor	Advanced renal cell carcinoma	03/10/2021	S
6 Piflufolastat F-18 (Pylarify)	Progenics	¹⁸ F labelled prostate-specific membrane antigen (PSMA) imaging agent	Prostate cancer imaging	05/26/2021	P
7 Infigratinib phosphate (Truseltiq)	Helsinn Hlthcare	FGFR1-3 inhibitor	Advanced cholangiocarcinoma with <i>FGFR2</i> fusions/rearrangements	05/28/2021	P, O
8 Sotorasib (Lumakras)	Amgen	KRAS ^{G12C} inhibitor	KRAS ^{G12C} -mutated NSCLC	05/28/2021	P, O
9 Mobocertinib succinate (Exkivity)	Takeda	EGFR kinase inhibitor	EGFR exon 20-mutated NSCLC	09/15/2021	P, O
10 Asciminib HCl (Scemblix)	Novartis	ABL/BCR-ABL1 kinase inhibitor	Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML)	10/29/2021	P, O
11 Pafolacianine sodium (Cytalux)	On Target Labs	Fluorescent folate receptor α (FRα) imaging agent	Ovarian cancer imaging	11/29/2021	P, O
2021 Biologics license applications = 5					
1 Dostarlimab (Jemperli)	GlaxoSmithKline	PD1-directed mAb	Endometrial cancer	04/22/2021	P
2 Loncastuximab tesirine (Zynlonta)	ADC Therapeutics	CD19-directed ADC	B-cell lymphoma	04/23/2021	P, O
3 Amivantamab (Rybrevant)	Janssen Biotech	EGFR- and MET-bispecific antibody	EGFR exon 20-mutated NSCLC	05/21/2021	P
4 Asparaginase erwinia chrysanthemii (Rylaze)	Jazz	Recombinant asparagine-specific enzyme	Acute lymphoblastic leukaemia (ALL), and lymphoblastic lymphoma (LBL), in patients allergic to <i>E. coli</i> -derived products	06/30/2021	S, O
5 Tisotumab vedotin (Tivdak)	Seagen	Tissue-factor-targeted ADC	Cervical cancer	09/20/2021	P, O

Supplementary data: Table 3 – FDA-approved therapeutic drugs for solid tumors

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
Therapeutic drugs for lung cancers					
1 Vinorelbine tartrate (Navelbine)	Pierre Fabre	Microtubule-destabilizing agent	Non-small-cell lung cancer (NSCLC)	12/23/1994	P
2 Gefitinib (Iressa)	AstraZeneca	EGFR kinase inhibitor	Non-small-cell lung cancer (NSCLC)	05/05/2003	P
3 Erlotinib HCl (Tarceva)	OSI Pharms	EGFR inhibitor	Non-small-cell lung cancer (NSCLC)	11/18/2004	P
4 Crizotinib (Xalkori)	Merck & Co	Multi-target TKI (ALK, ROS1, and MET)	ALK-positive advanced or metastatic NSCLC	08/26/2011	P, O
5 Afatinib dimaleate (Gilotrif)	Boehringer Ingelheim	EGFR, HER2, and HER4 inhibitor	Metastatic NSCLC with <i>EGFR</i> exon 19 deletions or exon 21 (L858R) substitution mutations	07/12/2013	P, O
6 Ceritinib (Zykadia)	Novartis	Multi-target TKI (ALK, IGF1R, INSR, and ROS1)	ALK-positive metastatic NSCLC	04/29/2014	P, O
7 Osimertinib mesylate (Tagrisso)	AstraZeneca	EGFR inhibitor	NSCLC with <i>EGFR</i> ^{T790M} mutations	11/13/2015	P, O
8 Necitumumab (Portrazza)	Eli Lilly & Co	EGFR-directed mAb	Non-small-cell lung cancer (NSCLC)	11/24/2015	S, O
9 Alectinib HCl (Alecensa)	Roche	ALK inhibitor	Non-small-cell lung cancer (NSCLC)	12/11/2015	P, O
10 Brigatinib (Alunbrig)	Takeda	Multi-target TKI (ALK, EGFR, IGF1R, FLT3, and ROS1)	ALK-positive NSCLC	04/28/2017	P, O
11 Dacomitinib (Vizimpro)	Pfizer	EGFR inhibitor	<i>EGFR</i> -mutated NSCLC	09/27/2018	P, O
12 Lorlatinib (Lorbrena)	Pfizer	Multi-target TKI (ALK and ROS1)	ALK-positive NSCLC	11/02/2018	P, O
13 Entrectinib (Rozlytrek)	Genentech	Multi-target TKI (TRKs, ROS1, and ALK)	NTRK fusion- positive solid tumors and ROS1-positive NSCLC	08/15/2019	P, O
14 Capmatinib HCl (Tabrecta)	Novartis	MET kinase inhibitor	Non-small-cell lung cancer (NSCLC)	05/06/2020	P, O
15 Selpercatinib (Retevmo)	Loxo Oncology	RET kinase inhibitor	RET fusion-positive NSCLC and thyroid cancer	05/08/2020	P, O
16 Pralsetinib (Gavreto)	Genentech	RET kinase inhibitor	RET fusion-positive NSCLC	09/04/2020	P, O
17 Tepotinib HCl (Tepmetko)	Emd Serono	MET kinase inhibitor	Non-small-cell lung cancer (NSCLC)	02/03/2021	P, O
18 Amivantamab (Rybrevant)	Janssen Biotech	EGFR- and MET-bispecific antibody	<i>EGFR</i> exon 20-mutated NSCLC	05/21/2021	P
19 Sotorasib (Lumakras)	Amgen	KRAS ^{G12C} inhibitor	KRAS ^{G12C} -mutated NSCLC	05/28/2021	P, O
20 Mobocertinib succinate (Exkivity)	Takeda	EGFR kinase inhibitor	<i>EGFR</i> exon 20-mutated NSCLC	09/15/2021	P, O
21 Topotecan HCl (Hycamtin)	Novartis	DNA topoisomerases inhibitor	Relapsed small cell lung cancer	05/28/1996	P
22 Lurbinectedin (Zepzelca)	Jazz	DNA alkylating drug	Small-cell lung cancer	06/15/2020	P, O

Supplementary data: Table 3 – FDA-approved therapeutic drugs for solid tumors (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
Therapeutic drugs for breast cancers					
1 Anastrozole (Arimidex)	Ani Pharms	Aromatase inhibitor	Advanced breast cancer in post-menopausal women	12/27/1995	S
2 Docetaxel (Taxotere)	Sanofi	Microtubule-stabilizing agent	Locally advanced or metastatic breast cancer	05/14/1996	P
3 Toremifene citrate (Fareston)	Kyowa kirin	Estrogen receptor (ER) inhibitor	ER-positive metastatic breast cancer	05/29/1997	S, O
4 Letrozole (Femara)	Novartis	Aromatase inhibitor	Advanced breast cancer	07/25/1997	S
5 Capecitabine (Xeloda)	Roche	Prodrug of 5-FU	Metastatic breast cancer	04/30/1998	P
6 Trastuzumab (Herceptin)	Genentech	HER2-directed mAb	HER2-positive breast cancer	09/25/1998	P
7 Epirubicin HCl (Ellence)	Pfizer	DNA topoisomerase II inhibitor	Primary breast cancer with axillary node tumor involvement	09/15/1999	P, O
8 Exemestane (Aromasin)	Pfizer	Aromatase inhibitor	ER-positive early breast cancer	10/21/1999	S, O
9 Fulvestrant (Faslodex)	AstraZeneca	Estrogen receptor antagonist	HR-positive metastatic breast cancer	04/25/2002	S
10 Lapatinib Ditosylate (Tykerb)	Novartis	HER2 and EGFR inhibitor	Advanced or metastatic breast cancer (HER2-positive)	03/13/2007	P
11 Ixabepilone (Ixempra)	R-Pharm US	Microtubule-stabilizing agent	Advanced or metastatic breast cancer	10/16/2007	P
12 Eribulin mesylate (Halaven)	Eisai	Microtubule-destabilizing agent	Breast cancer	11/15/2010	P
13 Pertuzumab (Perjeta)	Genentech	HER2-directed mAb	HER2-positive metastatic breast cancer	06/08/2012	P
14 Ado-trastuzumab emtansine (Kadcyla)	Genentech	HER2-directed ADC	HER2-positive metastatic breast cancer	02/22/2013	P
15 Palbociclib (Ibrance)	Pfizer	Cyclin-dependent kinase 4/6 (CDK4/6) inhibitor	HER2-negative and HR-positive advanced or metastatic breast cancer	02/03/2015	P
16 Ribociclib succinate (Kisqali)	Novartis	CDK4/6 inhibitor	HR-positive, HER2-negative breast cancer	03/13/2017	P
17 Neratinib maleate (Nerlynx)	Puma Biotech	EGFR, HER2, and HER4 inhibitor	HER2-overexpressed breast cancer	07/17/2017	S
18 Abemaciclib (Verzenio)	Eli Lilly & Co	CDK4/6 inhibitor	HR-positive, HER2-negative breast cancer	09/28/2017	P
19 Talazoparib tosylate (Talzenna)	Pfizer	Poly-ADP ribose polymerase (PARP) inhibitor	BRCA-mutated HER2-negative breast cancer	10/16/2018	P
20 Alpelisib (Piqray)	Novartis	Phosphatidylinositol 3-kinase α (PI3K α) inhibitor	Breast cancer	05/24/2019	P
21 Trastuzumab deruxtecan (Enhertu)	Daiichi Sankyo	HER2-directed antibody-drug conjugate (ADC)	HER2-positive breast cancer	12/20/2019	P
22 Tucatinib (Tukysa)	Seagen	HER2 inhibitor	HER2-positive breast cancer	04/17/2020	P, O
23 Sacituzumab govitecan (Trodelvy)	Immunomedics Inc	Trophoblast cell surface antigen 2 (Trop2)-directed ADC	Triple-negative breast cancer	04/22/2020	P
24 Margetuximab (Margenza)	MacroGenics	HER2-directed mAb	HER2-positive breast cancer	12/16/2020	S

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
Therapeutic drugs for gynecologic cancers					
1 Paclitaxel (Taxol)	HQ Spclt Pharma	Microtubule-stabilizing agent	Advanced ovarian cancer	12/29/1992	P, O
2 Olaparib (Lynparza)	AstraZeneca	PARP inhibitor	Advanced BRCA-mutated ovarian cancer	12/19/2014	P, O
3 Rucaparib camsylate (Rubraca)	Clovis Oncology	PARP inhibitor	BRCA-positive ovarian cancer	12/19/2016	P, O
4 Niraparib tosylate (Zejula)	GlaxoSmithKline	Poly-ADP ribose polymerase (PARP) inhibitor	Epithelial ovarian, fallopian tube or primary peritoneal cancer	03/27/2017	P, O
5 Dostarlimab (Jemperli)	GlaxoSmithKline	PD1-directed mAb	Endometrial cancer	04/22/2021	P
6 Tisotumab vedotin (Tivdak)	Seagen	Tissue-factor-targeted ADC	Cervical cancer	09/20/2021	P, O

Supplementary data: Table 3 – FDA-approved therapeutic drugs for solid tumors (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
Therapeutic drugs for gastrointestinal cancers					
1 Porfimer sodium (Photofrin)	Pinnacle Biologics	A photosensitizer used for photodynamic therapy	Advanced esophageal cancer	12/27/1995	P, O
2 Ramucirumab (Cyramza)	Eli Lilly & Co	VEGFR2-targeted mAb	Gastric cancer	04/21/2014	P, O
3 Sunitinib malate (Sutent)	CPPI CV	Multi-target TKI (VEGFRs, PDGFR α/β , CSF1R, KIT, and FLT3)	Imatinib-resistant gastrointestinal stromal tumor and advanced renal cell carcinoma	01/26/2006	P
4 Avapritinib (Ayvakit)	Blueprint Medicines	PDGFR α , PDGFR α mutants, and KIT inhibitor	Gastrointestinal stromal tumor (GIST) with <i>PDGFRA</i> exon 18 mutations	01/09/2020	P, O
5 Ripretinib (Qinlock)	Deciphera	PDGFR α , PDGFR α mutants, and KIT inhibitor	Advanced gastrointestinal stromal tumor (GIST)	05/15/2020	P, O
6 Lutetium dotatate Lu-177 (Lutathera)	AAA USA Inc	Somatostatin receptor-targeted radiopharmaceutical	Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)	01/26/2018	P, O
7 Pemigatinib (Pemazyre)	Incyte	Fibroblast growth factor receptor 1-3 (FGFR1-3) kinase inhibitor	Advanced cholangiocarcinoma with <i>FGFR2</i> fusions/rearrangements	04/17/2020	P, O
8 Infigratinib phosphate (Truseltiq)	Helsinn Healthcare	FGFR1-3 inhibitor	Advanced cholangiocarcinoma with <i>FGFR2</i> fusions/rearrangements	05/28/2021	P, O
9 Gemcitabine HCl (Gemzar)	Eli Lilly	DNA synthesis inhibitor	Locally advanced or metastatic pancreatic cancer	05/15/1996	P
10 Irinotecan HCl (Camptosar)	Pfizer	Topoisomerase I inhibitor	Metastatic colorectal cancer	06/14/1996	P
11 Oxaliplatin (Eloxatin)	Sanofi	Organoplatinum alkylating agent, increases tumor response rate to chemotherapy	Colorectal cancer (in combination with 5-FU and leucovorin)	08/09/2002	P
12 Cetuximab (Erbix)	ImClone	EGFR-directed mAb	Colorectal cancer	02/12/2004	N/A
13 Bevacizumab (Avastin)	Genentech	VEGF-A-directed mAb	Colorectal cancer	02/26/2004	O
14 Panitumumab (Vectibix)	Amgen	EGFR-directed mAb	EGFR-expressing metastatic colorectal carcinoma	09/27/2006	N/A
15 Ziv-aflibercept (Zaltrap)	Sanofi	Soluble receptor decoy that binds VEGF-A, VEGF-B, and PlGF	Metastatic colorectal cancer	08/03/2012	P
16 Regorafenib (Stivarga)	Bayer	Multi-target TKI (RET, VEGFRs, KIT, PDGFR α/β , FGFR1/2, RAF1, BRAFWT, and BRAFV600E)	Metastatic colorectal cancer	09/27/2012	P
17 Tipiracil HCl; Trifluridine (Lonsurf)	Taiho Oncology	Thymidine phosphorylase inhibitor plus a nucleoside metabolic inhibitor	Colorectal cancer	09/22/2015	S

Supplementary data: Table 3 – FDA-approved therapeutic drugs for solid tumors (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
Therapeutic drugs for prostate cancers					
1 Bicalutamide (Casodex)	Ani Pharms	Androgen receptor antagonist	Advanced prostate cancer	10/04/1995	S
2 Nilutamide (Nilandron)	Concordia	Androgen receptor antagonist	Metastatic prostate cancer	09/19/1996	S
3 Triptorelin pamoate (Trelstar)	Verity	GnRH agonist	Advanced prostate cancer	06/15/2000	S
4 Abarelix (Plenaxis)	Speciality European	GnRH receptor antagonist	Advanced prostate cancer	11/25/2003	P
5 Degarelix acetate (Firmagon)	Ferring	GnRH receptor antagonist	Advanced prostate cancer	12/24/2008	S
6 Cabazitaxel (Jevtana kit)	Sanofi	Microtubule-stabilizing agent	Prostate cancer	06/17/2010	P
7 Abiraterone acetate (Zytiga)	Janssen Biotech	CYP17A1 inhibitor	Metastatic castration-resistant prostate cancer	04/28/2011	P
8 Enzalutamide (Xtandi)	Astellas	Androgen receptor inhibitor	Metastatic castration-resistant prostate cancer	08/31/2012	P
9 Radium Ra-223 dichloride (Xofigo)	Bayer	α -particle-emitting radioactive therapeutic	Castration-resistant prostate cancer	05/15/2013	P
10 Apalutamide (Erleada)	Janssen Biotech	Androgen receptor inhibitor	Prostate cancer	02/14/2018	P
11 Darolutamide (Nubeqa)	Bayer	Androgen receptor inhibitor	Prostate cancer	07/30/2019	P
12 Relugolix (Orgovyx)	Myovant Sciences	GnRH receptor antagonist	Prostate cancer	12/18/2020	P

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
Therapeutic drugs for urologic cancers					
1 Aldesleukin (Proleukin)	Chiron	Recombinant human interleukin-2	Metastatic renal cell carcinoma	05/05/1992	O
2 Sorafenib tosylate (Nexavar)	Bayer	Multi-target TKI (VEGFR2/3, PDGFR β , FLT3, KIT, RAF1, and BRAF)	Advanced renal cell carcinoma	12/01/2005	P, O
3 Temsirolimus (Torisel)	Merck & Co	Mammalian target of rapamycin (mTOR) inhibitor	Advanced renal cell carcinoma	05/30/2007	P, O
4 Everolimus (Afinitor)	Novartis	Mammalian target of rapamycin (mTOR) inhibitor	Advanced renal cell carcinoma	03/30/2009	P
5 Pazopanib HCl (Votrient)	Novartis	Multi-target TKI (VEGFRs, PDGFR α/β , FGFR1/2, KIT)	Advanced renal cell carcinoma	10/19/2009	S
6 Axitinib (Inlyta)	Pfizer	VEGFRs inhibitor	Advanced renal cell carcinoma	01/27/2012	S
7 Tivozanib HCl (Fotivda)	Aveo Pharms	VEGFRs inhibitor	Advanced renal cell carcinoma	03/10/2021	S
8 Atezolizumab (Tecentriq)	Genentech	PDL1-directed mAb	Advanced or metastatic urothelial carcinoma	05/18/2016	P
9 Durvalumab (Imfinzi)	AstraZeneca	PDL1-directed mAb	Urothelial carcinoma	05/01/2017	P
10 Enfortumab vedotin (Padcev)	Astellas	Nectin-4-directed antibody-drug conjugate (ADC)	Urothelial carcinoma	12/18/2019	P
11 Valrubicin (Valstar)	Endo Pharm	A semisynthetic analog of anthracycline doxorubicin	BCG-refractory CIS of urinary bladder cancer	09/25/1998	P, O
12 Erdafitinib (Balversa)	Janssen Biotech	Fibroblast growth factor receptor (FGFR) inhibitor	Bladder cancer	04/12/2019	P

Supplementary data: Table 3 – FDA-approved therapeutic drugs for solid tumors (Continued)

Drug (brand name)	Sponsor	Properties	Indication	Approval date	Review
Therapeutic drugs for melanoma and other skin cancers					
1 Ipilimumab (Yervoy)	Bristol-Myers Squibb	Cytotoxic T-lymphocyte antigen 4 (CTLA-4)-directed mAb	Unresectable or metastatic melanoma	03/25/2011	P, O
2 Vemurafenib (Zelboraf)	Roche	BRAF inhibitor	BRAF-positive unresectable or metastatic melanoma	08/17/2011	P, O
3 Dabrafenib mesylate (Tafinlar)	Novartis	Kinase inhibitor with activity against BRAF ^{V600E/D/K} , wild-type BRAF and other kinases	Unresectable or metastatic melanoma with BRAF ^{V600E} mutation	05/29/2013	S, O
4 Trametinib dimethyl sulfoxide (Mekinist)	Novartis	MEK1 and MEK2 kinase inhibitor	Unresectable or metastatic melanoma with BRAF ^{V600E} mutation	05/29/2013	S, O
5 Pembrolizumab (Keytruda)	Merck & Co	PD1-directed mAb	Metastatic melanoma	09/04/2014	P, O
6 Nivolumab (Opdivo)	Bristol-Myers Squibb	PD1-directed mAb	Unresectable or metastatic melanoma	12/22/2014	P, O
7 Cobimetinib fumarate (Cotellic)	Genentech	MEK inhibitor	Melanoma with BRAF ^{V600E/K} mutations	11/10/2015	P, O
8 Encorafenib (Braftovi)	Array BioPharma	BRAF inhibitor	BRAF-mutated melanoma	06/27/2018	S, O
9 Binimetinib (Mektovi)	Array BioPharma	MEK inhibitor	BRAF-mutated melanoma	06/27/2018	S, O
10 Vismodegib (Erivedge)	Genentech	Smoothened (Hedgehog pathway) inhibitor	Metastatic or locally advanced basal cell carcinoma	01/30/2012	P
11 Sonidegib phosphate (Odomzo)	Sun Pharma Global	Smoothened inhibitor	Basal cell carcinoma	07/24/2015	S
12 Avelumab (Bavencio)	Emd Serono	PDL1-directed mAb	Merkel cell carcinoma	03/23/2017	P, O
13 Cemiplimab (Libtayo)	Regeneron Pharmaceuticals	Programmed death receptor-1 (PD1)-directed mAb	Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)	09/28/2018	P
Therapeutic drugs for thyroid cancers and other solid tumors					
1 Thyrotropin alfa (Thyrogen)	Genzyme	Recombinant human thyroid stimulating hormone	Diagnostic testing for thyroid tissue remnants following radioiodine ablation, and alongside radioactive agents to destroy thyroid tissue	11/30/1998	O
2 Vandetanib (Caprelsa)	Genzyme	Multi-target TKI (VEGFR2/3, EGFR, and RET)	Unresectable or metastatic medullary thyroid cancer	04/06/2011	P, O
3 Cabozantinib S-malate (Cometriq)	Exelixis	Multi-target TKI (VEGFRs, MET, RET, FLT3, KIT, TIE2, and AXL)	Progressive, metastatic medullary thyroid cancer	11/29/2012	P, O
4 Lenvatinib mesylate (Lenvima)	Eisai	Multi-target TKI (VEGFRs, FGFRs, PDGFR α , RET, and KIT)	Thyroid cancer	02/13/2015	P, O
5 Alitretinoin (Panretin)	Concordia	9-cis-retinoic acid, a form of vitamin A	AIDS-related Kaposi's sarcoma	02/02/1999	P, O
6 Temozolomide (Temodar)	Merck & Co	DNA alkylating agent	Glioblastoma	08/11/1999	P, O
7 Dinutuximab (Unituxin)	United Therap	GD2-directed mAb	High-risk neuroblastoma	03/10/2015	P, O
8 Naxitamab (Danyelza)	Y-mAbs Therapeutics	GD2-directed mAb	High-risk neuroblastoma	11/25/2020	P, O
9 Pemetrexed disodium (Alimta)	Eli Lilly	Folate analog	Malignant pleural mesothelioma	02/04/2004	P, O
10 Trabectedin (Yondelis)	Janssen Prods	Alkylating drug, interacts with the minor groove of DNA	Liposarcoma or leiomyosarcoma	10/23/2015	P, O
11 Olaratumab (Lartruvo)	Eli Lilly & Co	PDGFR α -directed mAb	Soft tissue sarcoma	10/19/2016	P, O
12 Larotrectinib sulfate (Vitrakvi)	Bayer	TRKs inhibitor	NTRK-positive solid cancers	11/26/2018	P, O
13 Pexidartinib HCl (Turalio)	Daiichi Sankyo	CSF1R, KIT, and FLT3 inhibitor	Tenosynovial giant cell tumor	08/02/2019	P, O
14 Tazemetostat (Tazverik)	Epizyme Inc	Enhancer of Zeste Homolog 2 (EZH2) inhibitor	Epithelioid sarcoma	01/23/2020	P, O

Supplementary data: Table 4 – ICBs: first approval and primary indications in the USA and China

Drug (brand name)	Sponsor	Target	IgG type	Primary indication	Approval date
Food and Drug Administration (USA), N = 9					
1 Ipilimumab (Yervoy)	Bristol-Myers Squibb	CTLA-4	IgG1 κ	Malignant melanoma	03/25/2011
2 Pembrolizumab (Keytruda)	Merck	PD-1	IgG4 κ	Advanced, unresectable or metastatic melanoma	09/04/2014
3 Nivolumab (Opdivo)	Bristol-Myers Squibb	PD-1	IgG4 κ	Unresectable or metastatic melanoma	12/22/2014
4 Atezolizumab (Tecentriq)	Genentech	PD-L1	IgG1 κ	Urothelial carcinoma	05/18/2016
5 Avelumab (Bavencio)	Emd Serono	PD-L1	IgG1 λ	Metastatic Merkel cell carcinoma	03/23/2017
6 Durvalumab (Imfinzi)	AstraZeneca	PD-L1	IgG1 κ	Locally advanced or metastatic urothelial carcinoma	05/01/2017
7 Cemiplimab (Libtayo)	Regeneron	PD-1	IgG4 κ	Locally advanced or metastatic Cutaneous squamous cell carcinoma	09/28/2018
8 Dostarlimab (Jemperli)	GlaxoSmithKline	PD-1	IgG4 κ	Mismatch repair deficient, recurrent or advanced endometrial cancer	04/22/2021
9 Nivolumab/Relatlimab (Opdualag)	Bristol-Myers Squibb	PD-1/LAG-3	IgG4 κ	Unresectable or metastatic melanoma	03/18/2022
National Medical Products Administration (China), N = 11					
10 Toripalimab (Tuoyi)	Junshi Bio	PD-1	IgG4	Unresectable or metastatic melanoma	12/17/2018
11 Sintilimab (Tyvyt)	Innovent Bio, Eli Lilly	PD-1	IgG4	Relapsed or refractory classical Hodgkin's lymphoma	12/27/2018
12 Camrelizumab (艾利可)	Hengrui Med	PD-1	IgG4 κ	Relapsed or refractory classical Hodgkin's lymphoma	05/31/2019
13 Tislelizumab (百泽安)	BeiGene	PD-1	IgG4	Relapsed or refractory classical Hodgkin's lymphoma	12/26/2019
14 Penpulimab (安尼可)	Akeso Bio, Chia Tai Tianqing	PD-1	IgG1	Relapsed or refractory classical Hodgkin's lymphoma	08/05/2021
15 Zimberelimab (誉妥)	Gloria Bio, Arcus Bio, Taiho Pharma	PD-1	IgG4	Relapsed or refractory classical Hodgkin's lymphoma	08/25/2021
16 Envafohimab (恩维达)	Alphamab Oncology	PD-L1	Nanobody	Advanced mismatch repair deficient solid tumors	11/24/2021
17 Sugemalimab (Cejemly)	CStone Pharma	PD-L1	IgG4	<i>EGFR</i> ^{Mut} and <i>ALK</i> ^{Ne9} metastatic non-small cell lung cancer	12/21/2021
18 Serplulimab (汉斯状)	Henlius Bio	PD-1	IgG4	Advanced, unresectable or metastatic microsatellite instability-high solid tumors	03/25/2022
19 Cadonilimab (开坦尼)	Akeso Bio	PD-1/CTLA-4	IgG1	Relapsed or metastatic cervical cancer	06/29/2022
20 Pucotenimab (普佑恒)	Lepu Bio	PD-1	IgG4	Microsatellite instability-high solid tumors	07/22/2022

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