

New Drug and Therapeutic Biologic Approvals in 2015

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<u>Product</u>	<u>Company</u>	<u>Indication/Use</u>	<u>BLA/NDA Received**</u>	<u>FDA Approved</u>
Addyi® flibanserin (S) For more information: www.addyi.com	Sprout Pharmaceuticals Raleigh, NC	treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSSD)	10/27/2009 (NDA)	8/18/2015
Alecensa® alectinib (P, A, B) ORPHAN DRUG For more information: www.alecensa.com	Genentech South San Francisco, CA	treatment of metastatic anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) in patients who have progressed or are intolerant to treatment with Xalkori® (crizotinib)	7/16/2015 (NDA)	12/11/2015
Aristada® aripiprazole lauroxil (S) For more information: www.aristada.com	Alkermes Waltham, MA	treatment of schizophrenia	8/22/2014 (NDA)	10/5/2015
Avycaz® ceftazidime and avibactam (P) For more information: www.avycaz.com	Allergan Parsippany, NJ	treatment of complicated intra-abdominal infections (cIAI) in combination with metronidazole, and complicated urinary tract infections (cUTI), including kidney infections, caused by designated susceptible microorganisms	6/25/2014 (NDA)	2/25/2015
Bridion® sugammadex (P) For more information: www.merckconnect.com/bridion/overview.html	Merck Kenilworth, NJ	for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery	10/31/2007 (NDA)	12/15/2015
Cholbam® cholic acid (P) ORPHAN DRUG For more information: www.cholbam.com	Retrophin San Diego, CA	treatment of adults and children with bile acid synthesis disorders due to single enzyme defects and adjunctive treatment of peroxisomal disorders with liver disease, including Zellweger spectrum disorders	11/21/2013 (NDA)	3/17/2015

* Approved by the Center for Drug Evaluation and Research (CDER).

** Date application was received by CDER as stated in the FDA-issued Approval Letter.

(S) - Standard Review

(P) - Priority Review

(A) - Accelerated Approval

(B) - Breakthrough Therapy

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Corlanor® ivabradine (P) For more information: www.corlanor.com	Amgen Thousand Oaks, CA	to reduce hospitalization for worsening heart failure in persistent (chronic) heart failure	6/27/2014 (NDA)	4/15/2015
Cosentyx® secukinumab (S) For more information: www.cosentyx.com	Novartis Pharmaceuticals East Hanover, NJ	treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy	10/24/2013 (BLA)	1/21/2015
Cotellic® cobimetinib (P) ORPHAN DRUG For more information: www.cotellic.com	Genentech South San Francisco, CA	treatment of unresectable or metastatic melanoma with either the BRAF V600E or V600K gene mutation in combination with Zelboraf® (vemurafenib)	12/11/2014 (NDA)	11/10/2015
Cresemba® isavuconazonium sulfate (P) ORPHAN DRUG For more information: www.cresemba.com	Astellas Pharma US Northbrook, IL	treatment of invasive aspergillosis and invasive mucormycosis in adults	7/8/2014 (NDA)	3/6/2015
Daklinza™ daclatasvir (P) For more information: www.daklinza.bmscustomerconnect.com	Bristol-Myers Squibb Princeton, NJ	treatment of chronic hepatitis C virus, genotype 3 infection in combination with Solvadi® (sofosbuvir)	3/31/2014 (NDA)	7/24/2015
Darzalex™ daratumumab (P, A, B) ORPHAN DRUG For more information: www.darzalex.com	Janssen Biotech Horsham, PA	treatment of multiple myeloma in patients who have received at least three prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory agent, or who are double-refractory to a PI or immunomodulatory agent	7/9/2015 (BLA)	11/16/2015
Empliciti™ elotuzumab (P, B) ORPHAN DRUG For more information: www.empliciti.com	Bristol-Myers Squibb Princeton, NJ	treatment of multiple myeloma in combination with Revlimid® (lenalidomide) and dexamethasone in patients who have received one to three prior treatments	6/29/2015 (BLA)	11/30/2015

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Entresto® sacubitril/valsartan (P)	Novartis Pharmaceuticals East Hanover, NJ	treatment of heart failure with reduced ejection fraction	12/17/2014 (NDA)	7/7/2015
For more information: www.entresto.com				
Farydak® panobinostat (P, A) ORPHAN DRUG	Novartis Pharmaceuticals East Hanover, NJ	treatment of previously treated multiple myeloma in adults in combination with Velcade® (bortezomib) and dexamethasone after at least two other types of treatment have been tried	3/24/2014 (NDA)	2/23/2015
For more information: www.us.farydak.com				
Genvoya® elvitegravir, cobicistat, entricitabine, tenofovir alafenamide (P)	Gilead Sciences Foster City, CA	treatment of HIV-1 infection in adult and pediatric patients 12 years and older	11/5/2014 (NDA)	11/5/2015
For more information: www.genvoya.com				
Ibrance® palbociclib (P, A, B)	Pfizer New York, NY	first-line treatment in combination with letrozole for estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced breast cancer in post-menopausal women	8/13/2014 (NDA)	2/3/2015
For more information: www.ibrance.com				
Kanuma™ sebelipase alfa (P, B) ORPHAN DRUG	Alexion Pharmaceuticals Cheshire, CT	enzyme replacement therapy for the treatment of lysosomal acid lipase deficiency (LAL-D) (an ultra-rare metabolic disease)	1/8/2015 (BLA)	12/8/2015
For more information: www.kanuma.com				
Kengreal® cangrelor (S)	The Medicines Company Parsippany, NJ	for the reduction of perioperative thrombotic events in adults undergoing percutaneous coronary intervention (PCI)	12/23/2014 (NDA)	6/22/2015
www.kengreal.com (Product now marketed by Cheisi USA)				
Kybella® deoxycholic acid (S)	Allergan Parsippany, NJ	treatment of moderate to severe fat below the chin in adults (submental fat)	5/13/2014 (NDA)	4/29/2015
For more information: www.mykybella.com				

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Lenvima® lenvatinib (P) ORPHAN DRUG For more information: www.lenvima.com	Eisai Woodcliff Lake, NJ	treatment of locally recurrent or metastatic progressive, radioactive iodine-refractory differentiated thyroid cancer	8/14/2014 (NDA)	2/13/2015
Lonsurf® trifluridine and tipiracil (S) For more information: www.lonsurf.com	Taiho Oncology Princeton, NJ	treatment of metastatic colorectal cancer in patients who no longer respond to other therapies	12/19/2014 (NDA)	9/22/2015
Natpara® parathyroid hormone (S) ORPHAN DRUG For more information: www.natpara.com	Shire-NPS Pharmaceuticals Lexington, MA	an adjunct to calcium and vitamin D for the control of hypocalcemia in patients with hypoparathyroidism (a rare endocrine disorder)	10/24/2013 (BLA)	1/23/2015
Ninlaro® ixazomib (P) ORPHAN DRUG For more information: www.ninlaro.com	Takeda Oncology Cambridge, MA	for the treatment of multiple myeloma in combination with Revlimid® (lenalidomide) and dexamethasone in patients who have received at least one prior treatment	7/10/2015 (NDA)	11/20/2015
Nucala® mepolizumab (S) For more information: www.ninlaro.com	GlaxoSmithKline Research Triangle Park, NC	add-on maintenance treatment of severe asthma in patients 12 years and older with the eosinophilic phenotype	11/4/2014 (BLA)	11/4/2015
Odomzo® sonidegib (S) For more information: www.odomzo.com	Novartis Pharmaceuticals East Hanover, NJ	treatment of locally advanced basal cell carcinoma that has recurred following surgery or radiation, or in patients who are not candidates for surgery or radiation	9/26/2014 (NDA)	7/24/2015
Orkambi® lumacaftor/ivacaftor (P, B) ORPHAN DRUG For more information: www.orkambi.com	Vertex Pharmaceuticals Boston, MA	treatment of cystic fibrosis in patients with two copies of the <i>F508del</i> gene mutation	11/5/2014 (NDA)	7/2/2015

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Portrazza™ necitumumab (S) ORPHAN DRUG For more information: www.portrazza.com	Eli Lilly Indianapolis, IN	treatment in combination with gemcitabine and cisplatin for advanced metastatic squamous NSCLC	12/2/2014 (BLA)	11/24/2015
Praluent® alirocumab (P) For more information: www.praluent.com	Regeneron Pharmaceuticals Tarrytown, NY Sanofi US Bridgewater, NJ	treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, such as heart attacks or strokes, who require additional lowering of LDL cholesterol (LDL-C)	11/24/2014 (BLA)	7/24/2015
Praxbind® idarucizumab (P, A, B) For more information: www.praxbind.com	Boehringer-Ingelheim Pharmaceuticals Ridgefield, CT	reversal of the blood thinning effects of Pradaxa® (dabigatran etexilate) for use in emergency surgery/urgent procedures or in life-threatening or uncontrolled bleeding	2/19/2015 (BLA)	10/16/2015
Repatha® evolocumab (S) For more information: www.repatha.com	Amgen Thousand Oaks, CA	treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease who require additional lowering of LDL-C and treatment of patients with homozygous familial hypercholesterolemia who require additional lowering of LDL-C	8/27/2014 (BLA)	8/27/2015
Rexulti® brexpiprazole (S) For more information: www.rexulti.com	Lundbeck Deerfield, IL Otsuka America Pharmaceutical Rockville, MD	treatment of schizophrenia in adults and as add-on treatment to anti-depressant therapy in adults with major depressive disorder	7/11/2014 (NDA)	7/10/2015
Savaysa® edoxaban (S) For more information: www.savaysa.com	Daiichi Sankyo Parsippany, NJ	reduction of stroke and systemic embolism in non-valvular atrial fibrillation and treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE)	1/8/2014 (NDA)	1/8/2015
Strensiq® asfotase alfa (P, B) ORPHAN DRUG For more information: www.strensiq.com	Alexion Pharmaceuticals Cheshire, CT	treatment of perinatal-, infantile- and juvenile-onset hypophosphatasia (an ultra-rare metabolic disease)	12/23/2014 (BLA)	10/23/2015

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Tagrisso™ osimertinib (P, A, B) ORPHAN DRUG For more information: www.tagrisso.com	AstraZeneca Wilmington, DE	treatment of NSCLC in patients with epidermal growth factor receptor (EGFR) T790M gene mutation and whose disease has gotten worse after treatment with other EGFR-blocking therapy	6/5/2015 (NDA)	11/13/2015
Tresiba® insulin degludec (S) For more information: www.tresiba.com	Novo Nordisk Plainsboro, NJ	for use alone, or in combination, for glycemic control in adults with type 1 and type 2 diabetes	9/29/2011 (NDA)	9/25/2015
Unituxin® dinutuximab (P) ORPHAN DRUG For more information: www.unituxin.com	United Therapeutics Silver Spring, MD	first-line treatment of high-risk pediatric neuroblastoma	4/11/2014 (BLA)	3/10/2015
Uptravi® selexipag (S) ORPHAN DRUG For more information: www.uptravi.com	Actelion Pharmaceuticals South San Francisco, CA	treatment of pulmonary arterial hypertension (PAH) in adults	12/22/2014 (NDA)	12/21/2015
Varubi® rolapitant (S) For more information: www.varubirx.com	Tesaro Waltham, MA	prevention of delayed chemotherapy-induced nausea and vomiting (CINV) in adults	9/5/2014 (NDA)	9/1/2015
Veltassa® patiromer (S) For more information: www.veltassa.com	Relypsa Redwood City, CA	treatment of hyperkalemia (a condition when potassium levels are too high in the blood)	10/21/2014 (NDA)	10/21/2015
Viberzi™ eluxadoline (P) For more information: www.viberzi.com	Allergan Parsippany, NJ Furiex Pharmaceuticals Morrisville, NC	treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults	6/27/2014 (NDA)	5/27/2015

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Vraylar® cariprazine (S) For more information: www.vraylar.com	Allergan Parsippany, NJ	treatment of schizophrenia and manic or mixed episodes of bipolar I disorder in adults	11/19/2012 (NDA)	9/17/2015
Xuriden™ uridine triacetate (P) ORPHAN DRUG For more information: www.xuriden.com	Wellstat Therapeutics Gaithersburg, MD	treatment of hereditary orotic aciduria (a rare metabolic disorder)	1/8/2015 (NDA)	9/4/2015
Yondelis® trabectedin (P) For more information: www.yondelis.com	Janssen Products Horsham, PA	treatment of unresectable or metastatic liposarcoma and leiomyosarcoma (two types of soft tissue sarcoma)	11/24/2014 (NDA)	10/23/2015
Zurampic® lesinurad (S) For more information: www.zurampic.com	Ardeo Biosciences San Diego, CA AstraZeneca Wilmington, DE	treatment of hyperuricemia (high levels of uric acid in the blood) associated with gout in combination with a xanthine oxidase inhibitor	12/29/2014 (NDA)	12/22/2015

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Adynovate antihemophilic factor (recombinant), PEGylated (S) For more information: www.adynovate.com	Baxalta (Shire) Bannockburn, IL	treatment of hemophilia A (congenital factor VIII deficiency) in patients 12 years and older for on-demand treatment and control of bleeding episodes and routine prevention to reduce the frequency of bleeding episodes	11/25/2014 (BLA)	11/13/2015
Anavip® Crotalidae immune F(ab') ₂ (equine) (S) For more information: www.raretx.com	Instituto Bioclon Toriello Guerra, Mexico Rare Disease Therapeutics Franklin, TN	management of North American rattlesnake envenomation in adult and pediatric patients	3/18/2013 (BLA)	5/6/2015

* Approved by the Center for Biologics Evaluation and Research (CBER).

** Date application was received by CBER as stated in the FDA Statistical Review.

(S) - Standard Review

(P) - Priority Review

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Anthrasil™ anthrax immune globulin intravenous (human) (P) ORPHAN DRUG	Emergent BioSolutions Gaithersburg, MD	treatment of inhalation anthrax in adult and pediatric patients in combination with appropriate antibacterial medicines	7/25/2014 (BLA)	3/24/2015
For more information: www.emergentbiosolutions.com				
Bexsero® meningococcal group B vaccine (P)	GlaxoSmithKline Research Triangle Park, NC	active immunization against invasive meningococcal disease caused by <i>Neisseria meningitidis</i> serogroup B in people 10 through 25 years of age	7/24/2014 (BLA)	1/23/2015
For more information: www.gsksource.com				
Coagadex® coagulation factor X (human) (P)	Bio Product Laboratory Durham, NC	replacement therapy for hereditary factor X deficiency in patients 12 years and older for on-demand treatment and control of bleeding episodes and perioperative management of bleeding in patients with mild hereditary factor X deficiency	7/11/2013 (BLA)	10/20/2015
For more information: www.coagadex.com				
Fluad™ influenza vaccine, adjuvanted (S)	Seqirus Holly Springs, NC	active immunization of adults 65 years and older against influenza disease caused by influenza virus subtypes A and B	11/25/2014 (BLA)	11/24/2015
For more information: www.fluad.com				
Imlygic® talimogene laherparepvec (S)	Amgen Thousand Oaks, CA	local treatment of unresectable cutaneous, subcutaneous and nodal lesions in patients with melanoma recurrence after initial surgery	7/28/2014 (BLA)	10/27/2015
For more information: www.imlygic.com				
Ixinity® coagulation factor IX (recombinant) (S)	Emergent BioSolutions Gaithersburg, MD	treatment of hemophilia B for control and prevention of bleeding episodes and perioperative management in adults and children age 12 years and older	4/6/2012 (BLA)	4/29/2015
For more information: www.ixinity.com (Product now marketed by Aptevo Therapeutics)				

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Nuwiq® simoctocag alfa (S) For more information: www.nuwiq.com	Octapharma USA Hoboken, NJ	treatment of hemophilia A in adults and children for on-demand treatment and control of bleeding episodes, management of bleeding and routine prevention to reduce frequency of bleeding episodes	6/5/2014 (BLA)	9/4/2015
Quadracel™ diphtheria and tetanus toxoids and acellular pertussis adsorbed and inactivated poliovirus vaccine (S) For more information: www.sanofipasteur.us	Sanofi Pasteur Swiftwater, PA	active immunization against diphtheria, tetanus, pertussis and poliomyelitis in children 4 through 6 years of age	3/24/2014 (BLA)	3/24/2015
Raplixa™ fibrin sealant (human) (S) For more information: www.mallinckrodt.com (Product is now owned by Mallinckrodt)	The Medicines Company Parsippany, NJ	adjunct to hemostasis for mild to moderate bleeding in adults undergoing surgery when control of bleeding by standard techniques (such as suture, ligature and cautery) is ineffective or impractical	1/31/2014 (BLA)	4/30/2015
Vonvendi von Willebrand factor (recombinant) (S) ORPHAN DRUG For more information: www.vonvendi.com	Baxalta (Shire) Bannockburn, IL	for on-demand treatment and control of bleeding episodes in adults with von Willebrand disease	12/19/2014 (BLA)	12/8/2015

The content of this survey has been obtained through government and industry sources. The information may not be comprehensive. For more specific information about a particular product, contact the individual company directly.

Definitions

Accelerated Approval—A program of the FDA, which allows early approval of a drug for serious or life-threatening illness that offers a benefit over current approved treatments. FDA bases its approval on a "surrogate endpoint" (e.g. a laboratory measure) or other clinical measure that is considered reasonably likely to predict clinical benefit. The medicine must undergo additional testing after approval to confirm the benefit.

BLA (Biologic License Application)—Application submitted by a sponsor to the FDA for approval of a new biologic for sale and marketing in the United States.

Breakthrough Therapy—Upon request by a sponsor, the FDA can grant this designation to expedite the development and review of a drug or biologic intended, along or in combination with one or more other drugs, to treat a serious or life threatening disease or condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically-significant endpoints, such as substantial treatment effects observed early in clinical development. If a drug or biologic is designated as a breakthrough therapy, the FDA will expedite the development and review. With this designation, all Fast Track features convey to the medicine.

NDA (New Drug Application)—Application submitted by a sponsor to the FDA for approval of a new pharmaceutical for sale and marketing in the United States.

Orphan Designation—Upon request by a sponsor, the FDA can grant special status (“orphan designation”) to a drug or biologic to treat a rare disease or condition. In order to receive an orphan designation, a qualifying drug or biologic must be intended for the treatment, diagnosis, or prevention of a rare disease or condition that usually affects fewer than 200,000 people in the United States.