

**Table 1: Novel drugs approved using one or more FDA expedited development and review methods, 2015 to 2017**

Year	Drug	Company	Therapy area	Accelerated Approval	Fast Track	Priority Review	Breakthrough Therapy	Orphan
2017	Aliqopa (copanlisib)	Bayer	To treat adults with relapsed follicular lymphoma	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Alunbrig (brigatinib)	Takeda	To treat patients with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Bavencio (avelumab)	EMD Serono	To treat metastatic Merkel cell carcinoma	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Baxdela (delafloxacin)	Melinta Therapeutics	To treat patients with acute bacterial skin infections	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Benznidazole (benznidazole)	Chemo Research	To treat children ages 2 to 12 years old with Chagas disease	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Besponsa (inotuzumab ozogamicin)	Pfizer	To treat adults with relapsed or refractory acute lymphoblastic leukemia	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Bevyxxa (betrixaban)	Portola Pharmaceuticals	For the prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Brineura (cerliponase alfa)	BioMarin	To treat a specific form of Batten disease	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Calquence (acalabrutinib)	AstraZeneca	To treat adults with mantle cell lymphoma	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Dupixent (dupilumab)	Regeneron Pharmaceuticals	To treat adults with moderate-to-severe eczema (atopic dermatitis)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Emflaza (deflazacort)	Marathon Pharmaceuticals	To treat patients age 5 years and older with Duchene muscular dystrophy (DMD)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Giapreza (angiotensin II)	La Jolla Pharmaceutical Company	To increase blood pressure in adults with septic or other distributive shock	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

2017	Hemlibra (emicizumab)	Genentech	To prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with haemophilia A who have developed antibodies called Factor VIII (FVIII) inhibitors	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Idhifa (enasidenib)	Celgene	To treat relapsed or refractory acute myeloid leukemia	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Imfinzi (durvalumab)	AstraZeneca	To treat patients with locally advanced or metastatic urothelial carcinoma	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Ingrezza (valbenazine)	Neurocrine Biosciences	To treat adults with tardive dyskinesia	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Kisqali (ribociclib)	Novartis	To treat postmenopausal women with a type of advanced breast cancer	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Mavyret (glecaprevir and pibrentasvir)	AbbVie	To treat adults with chronic hepatitis C virus	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Mepsevii (vestronidase alfa-vjkb)	Ultragenyx	To treat pediatric and adult patients with an inherited metabolic condition called mucopolysaccharidosis type VII (MPS VII) also known as Sly syndrome	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Ocrevus (ocrelizumab)	Genentech	To treat patients with relapsing and primary progressive form of multiple sclerosis	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Prevymis (Letermovir)	Merck	To prevent infection after bone marrow transplant	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Rydapt (midostaurin)	Novartis	To treat acute myeloid leukemia	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Solosec (secnidazole)	Symbiomix Therapeutics	To treat bacterial vaginosis	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Vabomere (meropenem and vaborbactam)	Rempex Pharmaceuticals	To treat adults with complicated urinary tract infections	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Verezenio (abemaciclib)	Eli Lilly	To treat certain advanced or metastatic breast cancers	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Vosevi (sofosbuvir, velpatasvir and voxilaprevir)	Gilead	To treat adults with chronic hepatitis C virus	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

2017	Xermelo (telotristat ethyl)	Lexicon Pharmaceuticals	To treat carcinoid syndrome diarrhea	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2017	Zeluja (niraparib)	Tesaro	For the maintenance treatment for recurrent epithelial ovarian, fallopian tube or primary peritoneal cancers	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2016	Anthim (obiltoximab)	Elysys Therapeutics	To treat inhalational anthrax in combination with appropriate antibacterial drugs	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2016	Axumin (fluciclovine)	Blue Earth Diagnostics	A new diagnostic imaging agent to detect recurrent prostate cancer	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2016	Defitelio (defibrotide sodium)	Jazz Pharmaceuticals	To treat adults and children who develop hepatic veno-occlusive disease with additional kidney or lung abnormalities after they receive a stem cell transplant from blood or bone marrow called hematopoietic stem cell transplantation	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2016	Epclusa (sofosbuvir and velpatasvir)	Gilead	To treat all six major forms of hepatitis C virus	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2016	Exondys 51 (eteplirsen)	Sarepta	To treat patients with Duchene muscular dystrophy	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2016	Lartruvo (olaratumab)	Eli Lilly	To treat adults with certain types of soft tissue sarcoma	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2016	Netspot (gallium Ga 68 dotatate)	Advanced Accelerator Applications	A diagnostic imaging agent to detect rare neuroendocrine tumors	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2016	Nuplazid (pimavanserin)	Acadia Pharmaceuticals	To treat hallucinations and delusions associated with psychosis experienced by some people with Parkinson's disease	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2016	Ocaliva (obeticholic acid)	Intercept Pharmaceuticals	To treat rare, chronic liver disease	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2016	Rubraca (rucaparib)	Clovis Oncology	To treat women with a certain type of ovarian cancer	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2016	Spinraza (nusinersen)	Biogen	To treat children and adults with spinal muscular atrophy (SMA)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2016	Tecentriq	Genentech	To treat urothelial carcinoma	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

	(atezolizumab)							
2016	Venclexta (venetoclax)	AbbVie	For chronic lymphocytic leukemia in patients with a specific chromosomal abnormality	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2016	Xiidra	Shire	To treat the signs and symptoms of dry eye disease	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2016	Zepatier (elbasvir and grazoprevir)	Merck	To treat patients with chronic hepatitis C virus (HCV) genotypes 1 and 4 infections in adult patients	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2016	Zinplava (besiotoxumab)	Merck	To reduce the recurrence of Clostridium difficile infection in patients aged 18 years or older	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Alecensa (alectinib)	Genentech	To treat ALK-positive lung cancer	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Avycaz (ceftazidime-avibactam)	Actavis Pharma	To treat adults with complicated intra-abdominal infections (cIAI), in combination with metronidazole, and complicated urinary tract infections (cUTI), including kidney infections (pyelonephritis), who have limited or no alternative treatment options	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Bridion (sugammadex)	Merck	To reverse effects of neuromuscular blocking drugs used during surgery	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Cholbam (cholic acid)	Asklepion Pharmaceuticals	To treat pediatric and adult patients with bile acid synthesis disorders due to single enzyme defects, and for patients with peroxisomal disorders	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Corlanor (ivabradine)	Amgen	To reduce hospitalization from worsening heart failure	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Cotellic (cobimetinib)	Genentech	To be used in combination with vemurafenib to treat advanced melanoma that has spread to other parts of the body or can't be removed by surgery, and that has a certain type of abnormal gene (BRAF V600E or V600K mutation)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Cresemba (isavuconazonium sulfate)	Astellas	To treat adults with invasive aspergillosis and invasive mucormycosis, rare but serious infections	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Daklinza (daclatasvir)	Bristol-Myers Squibb	To treat chronic hepatitis C virus (HCV) genotype 3 infections	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

2015	Darzalex (daratumumab)	Janssen	To treat patients with multiple myeloma who have received at least three prior treatments	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Empliciti (elotuzumab)	Bristol-Myers Squibb	To treat people with multiple myeloma who have received one to three prior medications	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Entresto (sacubitril/valsartan)	Novartis	To treat heart failure	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Farydak (panobinostat)	Novartis	To treat patients with multiple myeloma	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Ibrance (palbociclib)	Pfizer	To treat advanced (metastatic) breast cancer	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Kanuma (sebelipase alfa)	Alexion	To treat patients with a rare disease known as lysosomal acid lipase (LAL) deficiency	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Lenvima (lenvatinib)	Eisai	To treat patients with progressive, differentiated thyroid cancer (DTC) whose disease progressed despite receiving radioactive iodine therapy (radioactive iodine refractory disease)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Ninlaro (ixazomib)	Takeda	To treat people with multiple myeloma who have received at least one prior therapy	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Orkambi (lumacaftor 200mg/ivacaftor 125mg)	Vertex	To treat cystic fibrosis	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Praxbind (idarucizumab)	Boehringer Ingelheim	For use in patients who are taking the anticoagulant Pradaxa (dabigatran) during emergency situations when there is a need to reverse Pradaxa's blood-thinning effects	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Strensiq (asfotase alfa)	Alexion	To treat perinatal, infantile and juvenile-onset hypophosphatasia (HPP)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Tagrisso (osimerinib)	AstraZeneca	To treat certain patients with non-small cell lung cancer	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Unituxin (dinutuximab)	United Therapeutics	To treat pediatric patients with high-risk neuroblastoma	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Viberzi (eluxadoline)	Allergan	To treat irritable bowel syndrome with diarrhea (IBS-D) in adult men and women	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Xuriden (uridine)	Wellstat	To treat patients with hereditary orotic aciduria	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

	triacetate)	Therapeutics						
2015	Yondelis (trabectedin)	Janssen	To treat specific soft tissue sarcomas (STS) – liposarcoma and leiomyosarcoma – that cannot be removed by surgery (unresectable) or is advanced (metastatic)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Genvoya (a fixed-dose combination tablet containing elvitegravir, cobicistat, emtricitabine and tenofovir alafenamide)	Gilead	For use as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Lonsurf (trifluridine and tipiracil)	Taiho Oncology	To treat patients with advanced form of colorectal cancer who are no longer responding to other therapies	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2015	Portrazza (necitumumab)	Eli Lilly	To treat patients with advanced (metastatic) squamous non-small cell lung cancer (NSCLC) who have not previously received medication specifically for treating their advanced lung cancer	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

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