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New Drugs Approved in 2015

Generic/Trade/Manufacturer	Category	Use	Route	Warnings˚	Review Classification*
flibanserin Addyi™ **Sprout Pharm.**	Serotonin agonist/antagonist	Premenopausal women with hypoactive sexual desire disorder	Oral	BBWs: Use with alcohol is contraindicated Contraindicated in patients with hepatic impairment; use with moderate-strong CYP3A4 inhibitors REMS	S
alectinib Alecensa® **Genentech**	Antineoplastic agent	Treatment of anaplastic lymphoma kinase metastatic non-small cell lung cancer	Oral	Bradycardia Hepatotoxicity Myalgia	P
aripiprazole lauroxil Aristada™ **Alkermes**	Atypical antipsychotic	Treatment of schizophrenia	IM	BBW: Increased mortality in elderly patients	S
ceftazidime/avibactam Avycaz™ **Forest Labs**	Cephalosporin and beta-lactamase inhibitor	Treatment of complicated intra-abdominal and urinary tract infections	IV	Hypersensitivity reactions	P

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sugammadex Bridion® **Merck Sharp and Dohme Corp.**	Muscle relaxant	Reversal of neuromuscular blockade	IV	Hypersensitivity reactions	P
cholic acid Cholbam® **Asklepion Pharmaceuticals**	Bile acid replacement	Bile acid homeostasis in patients with genetic metabolic conditions	Oral	Hepatic impairment	P, O
ivabradine Corlanor® **Amgen**	Anti-anginal agent	Reduces hospitalization risk in patients with severe heart failure	Oral	Bradycardia Hypotension Increases risk for atrial fibrillation	P
secukinumab Cosentyx® **Novartis**	Immunologic agent	Treatment of moderate to severe plaque psoriasis	SQ	Hypersensitivity reactions	
cobimetinib Cotellic™ **Genentech**	Antineoplastic agent	Treatment of unresectable or malignant melanoma	Oral	Cardiomyopathy Dermatologic toxicity Hemorrhage Ophthalmic effects Rhabdomyolysis	P, O
isavuconazonium sulfate Cresemba® **Astellas**	Azole antifungal	Treatment of invasive aspergillosis and mucormycosis	Oral IV	Hypersensitivity reactions Avoid use with strong CYP3A4 inhibitors	P, O
daclatasvir Daklinza™ **Bristol-Myers Squibb**	Antiviral	Treatment of chronic hepatitis C infection	Oral	Avoid use with strong CYP3A4 inhibitors	P

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daratumumab Darzalex™ **Janssen Biotech**	Antineoplastic agent	Treatment of multiple myeloma	IV	Bone marrow suppression Infusion reactions	P, O
elotuzumab Empliciti™ **Bristol-Myers Squibb**	Antineoplastic agent	Treatment of multiple myeloma	IV	Hepatotoxicity Infusion reactions	O
sacubitril/valsartan Entresto™ **Novartis**	Antihypertensive combination	Treatment of chronic heart failure	Oral	BBW: Do not use if pregnant	P
panobinostat Farydak® **Novartis**	Antineoplastic agent	Treatment of multiple myeloma	Oral	BBWs: Severe GI events Severe cardiac ischemic events, arrhythmias and ECG changes REMS	P
elvitegravir, cobicistat, emtricitabine, tenofovir, alafenamide Genvoya® **Gilead Sciences**	Antiretroviral agents	Treatment of HIV-1	Oral	BBWs: Hepatitis B Lactic acidosis	S
palbociclib Ibrance® **Pfizer**	Antineoplastic agent	Treatment for advanced breast cancer	Oral	Bone marrow suppression	P
sebelipase alfa Kanuma™ **Alexion**	Enzyme replacement	Treatment of patients with lysosomal acid lipase deficiency	IV	None	
cangrelor Kengreal™ **The Medicines Co.**	Antiplatelet agent ($P2Y_{12}$ inhibitor)	Adjunct to PCI to reduce risk of MI	IV	Bleeding Hypersensitivity	S
deoxycholic acid Kybella®	Lipolytic agent	Reduces fat located below	SQ	Bruising/bleeding	S

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Kythera Biopharm.		the chin			
lenvatinib Lenvima™ **Eisai**	Antineoplastic agent	Treatment of thyroid cancer	Oral	Cardiac effects Hepatotoxicity Endocrine effects	P, O
tipiracil/trifluridine Lonsurf® **Taiho Oncology**	Antineoplastic agent	Treatment of metastatic colorectal cancer	Oral	Bone marrow suppression GI toxicity	S
parathyroid hormone Natpara® **NPS Pharm.**	Parathyroid hormone analog	Hypocalcemia in patients with hypoparathyroidism	SQ	BBW: Osteosarcoma risk	
ixazomib Ninlaro® **Takeda**	Antineoplastic agent	Treatment of multiple myeloma	Oral	Bone marrow suppression Dermatologic toxicity	P, O
mepolizumab Nucala® **GSK**	Anti-asthmatic monoclonal antibody	Add-on treatment for severe asthma/ eosinophilic inflammation	SQ	Hypersensitivity reactions	
sonidegib Odomzo® **Novartis**	Antineoplastic agent	Treatment of locally advanced basal cell carcinoma	Oral	BBW: embryo-fetal toxicity	S
lumacaftor/ivacaftor Orkambi® **Vertex Pharm.**	Metabolic agent for Cystic Fibrosis	Treatment of cystic fibrosis	Oral	Hepatic effects Respiratory effects	P
necitumumab Portrazza™ **Lilly**	Antineoplastic agent	Treatment of metastatic squamous non-small cell lung cancer	IV	BBWs: Cardiopulmonary arrest Hypomagnesemia	S, O

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alirocumab Praluent® **Sanofi-Aventis**	Antihyperlipidemic agent (PCSK9 Inhibitor)	Treatment of heterozygous familial hypercholester-olemia; clinical ASCVD	SQ	Hypersensitivity reactions	
idarucizumab Praxbind® **Boehringer Ingelheim**	Anticoagulant Reversal Agent	Reversal of anticoagulant effects of dabigatran	IV	Thromboembolic risk Hypersensitivity reactions	
evolocumab Repatha™ **Amgen**	Antihyperlipidemic agent (PCSK9 Inhibitor)	Adjunct treatment of hypercholester-olemia	SQ	Hypersensitivity reactions	
brexpiprazole Rexulti® **Otsuka America**	Atypical antipsychotic	Treatment of major depressive disorder and schizophrenia	Oral	BBWs: Increased mortality in elderly patients Suicidal thoughts and behavior	S
edoxaban Savaysa® **Daiichi Sankyo**	Anticoagulant (Factor Xa inhibitor)	Treatment of DVT/PE and reduce risk of stroke in patients with atrial fibrillation	Oral	BBWs: Increased risk of ischemic events if premature discontinuation Nonvalvular atrial fibrillation patients with CrCl < 95 mL/min Spinal/epidural hematomas	S
asfotase alfa Strensiq™ **Alexion**	Promotes bone mineralization	Treatment of hypophosphat-asia	SQ	Antibody formation Hypersensitivity reactions Lipodystrophy	

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osimertinib Tagrisso™ **AstraZeneca**	Antineoplastic agent	Treatment of metastatic non-small cell lung cancer	Oral	Bone marrow suppression Cardiovascular toxicity	P, O
insulin degludec Tresiba® **Novo Nordisk**	Long-acting insulin analog	Treatment of diabetes mellitus	SQ	Hypoglycemia Hypokalemia	S
dinutuximab Unituxin™ **United Therapeutics**	Antineoplastic agent	Treatment of high-risk neuroblastoma	IV	BBWs: Infusion reactions Neuropathy	
selexipag Uptravi® **Actelion**	Antihypertensive (Prostacyclin receptor agonist)	Treatment of pulmonary arterial hypertension	Oral	None	S, O
rolapitant Varubi™ **Tesaro**	Antiemetic	Treatment of delayed nausea and vomiting associated with chemotherapy	Oral	Concurrent use of thioridazine Hepatic impairment	S
patiromer Veltassa™ **Relypsa**	Potassium binder	Treatment of hyperkalemia	Oral	BBW: Binding to other oral medications	S
eluxadoline Viberzi® **Forest Pharm.**	Gastrointestinal Agent	Treatment of Irritable bowel syndrome - Diarrhea	Oral	C-IV Biliary duct obstruction Hepatic impairment Pancreatitis	P
cariprazine Vraylar™ **Actavis**	Atypical Antipsychotic Agent	Treatment of schizophrenia and Bipolar I disorder	Oral	BBW: Increased risk of mortality in elderly	S

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uridine triacetate Xuriden™ **Wellstat Therapeutics**	Antidote for fluorouracil overexposure	Treatment of hereditary orotic aciduria and fluoro-pyrimidine overdose/over-exposure	Oral	None	P, O
trabectedin Yondelis® **Janssen Biotech**	Antineoplastic agent	Treatment of soft tissue sarcoma	IV	Hypersensitivity reactions	P
lesinurad Zurampic® **AstraZeneca**	Anti-hyperuricemia	Treatment of Gout	Oral	BBW: Acute renal failure	S

*Review Classifications
P = priority drug review: appears to represent an advance over available therapy.
S = standard review drug: therapeutic qualities similar to those of an already marketed drug.
O = orphan drug.
˚BBW (Black Box Warning) REMS (Risk Evaluation and Mitigation Strategy)

The number of drugs approved by the U.S. Federal Drug Administration (FDA) continues to rise as the Center for Drug Evaluation and Research (CDER) approved 45 new molecular entities (NME) in 2015. This is a minor increase from last year's 41 new approvals but significant compared to the 30 new drugs approved in 2013 and the previous average approval rate of 28 new drugs per year. This rise in drug approvals has increased the number of unique drugs available, as more than a third of these new approvals are considered "first-in-class" or drugs that have a new mechanism of action for treating existing disease states.

The FDA approved more drugs to treat rare diseases in 2015 than any previous year in their history. About 40% of these new drugs are meant to help improve the lives of patients living with different cancers, cystic fibrosis, irritable bowel syndrome, and other uncommon medical conditions. With the addition of several new drugs for diseases with few treatment options, the United States has become a leader in approving new therapies for patients with life threatening and serious medical conditions.

Programs designed to streamline the drug approval process without compromising the integrity of it include designations for Fast Track, Breakthrough, Accelerated Approval, and Priority Review. Of the drugs approved in 2015, 60% are a part of one or more of these programs. Drugs approved through Fast Track and Breakthrough designations are required to fulfill an unmet medical need for patients with a serious condition, and these programs aim to provide therapy that will increase patient survival, daily functioning, and prevention of detrimental disease progression. Accelerated Approval focuses on drugs that will provide a meaningful

therapeutic benefit over current available therapies for serious diseases. Drugs in any of these programs may be considered for Priority Review, which requires the FDA to review a drug within a certain period of time.

Concerning warnings and approval classifications, two medications required a Risk Evaluation and Mitigation Strategy (REMS) compared to four medications last year, and 13 medications have a labeled black box warning (BBW) compared to 12 medications last year. This year 11 of the approved medications had orphan drug status, 19 were approved via priority drug review, and 16 were approved via standard review.

References

1. U.S. Food and Drug Administration: Drugs@FDA [Internet]. Silver Spring, MD; c2016 [cited 2016 Jan 5]. Available from: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.NewOriginalNDA
2. U.S. Food and Drug Administration: Frequently asked questions: breakthrough therapies [Internet]. Silver Spring, MD; c2016 [cited 2016 Jan 5]. Available from: http://www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAct/FDASIA/ucm341027.htm
3. U.S. Food and Drug Administration: Novel drugs summary 2015 [Internet]. Silver Spring, MD; c2016 [cited 2016 Jan 5]. Available from: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm474696.htm
4. Lexi-Comp Online [AUHSOP Intranet]. Hudson, OH: Wolters Kluwer Health/Lexi-Comp, Inc. [updated 2016, cited 2016 Jan 5]. [about 2 p.]. Available from http://online.lexi.com/lco/action/home/switch
5. Pharmacist's Letter [Internet]. Stockton: Therapeutic Research Center; c1995-2016. New Drugs Approved by the FDA in 2015; 2016 Jan 7 [cited 2016 Jan 7]; [about 8 screens]. Available from: http://pharmacistsletter.therapeuticresearch.com/pl/NewDrugs.aspx?s=PL&AspxAutoDetectCookieSupport=1

The last "dose" …

"Wherever the art of medicine is loved, there is also a love of humanity."
-Hippocrates [Greek Physician, 460 to 370 BC]

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