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New Drugs Approved in 2018

Generic Name Trade Name Manufacturer	Category	Use	Route	Warnings*	Review Classification*
amifampridine phosphate Firdapse® Catalyst Pharmaceuticals	Cholinergic agonist, potassium channel blocker	Lambert-Eaton Myasthenic Syndrome	PO	Seizures, HSR	O, B, P
apalutamide Erleada™ Janssen Oncology	Antineoplastic; antiandrogen	Prostate Cancer	PO	Falls and fractures, Seizures	Fa, P
avatrombopag Doptelet® Dova Pharmaceuticals	Colony stimulating factor, Hematopoietic agent, Thrombopoietin receptor agonist	Thrombocytopenia in adults with chronic liver disease who are scheduled to undergo a medical or dental procedure	PO	Thrombotic/ thromboembolic complications	P
baloxavir marboxil Xofluza™ Shionogi	Antiviral agent; Endonuclease inhibitor	Acute uncomplicated influenza	PO	Bacterial infection	P

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baricitinib Olumiant [®] Eli Lilly	Anti-rheumatic; Janus associated Kinase inhibitor	Rheumatoid arthritis	PO	BBW: Serious Infections like active tuberculosis, invasive fungal disease, candidiasis, esophageal candidiasis, acute histoplasmosis, multidermatomal, herpes zoster	S
bictegravir, embitcitabine, tenofovir alafenamide Biktarvy [®] Gilead	Antiretroviral, Integrase inhibitor, Reverse transcriptase inhibitor (nucleoside), Reverse transcriptase inhibitor (nucleotide)	HIV	PO	BBW: post treatment acute exacerbation of Hepatitis B Immune reconstitution syndrome, Renal impairment, Lactic acidosis	P
binimetinib Mektovi [®] Array BioPharma	Anti-neoplastic agent, MEK inhibitor	Melanoma, unresectable, metastatic	PO	Cardiomyopathy, VTE, Ocular toxicities, Hepatotoxicity, Interstitial lung disease	O
burosumab-twza Crysvita [®] Ultragen Pharmaceutical	Anti-FGF32 mAB	X-linked hypophosphatemia	SQ	HSR, Hyperphosphatemia and risk for nephrocalcinosis, Injection site reactions	Fi, O, Fa, B, P
calaspargase pegol-mknl Asparlas [™] Servier Pharmaceuticals	Anti-neoplastic agent; Asparagine specific	Acute Lymphocytic Anemia	IV	HSR, Pancreatitis, Thrombosis, Hemorrhage, Hepatotoxicity	O
cannabidiol Epidiolex [®] Greenwich Biosciences	Anticonvulsant	Seizures associated with Lennox-Gastaut syndrome and Dravet syndrome	PO	Hepatocellular injury, Somnolence and sedation, HSR	O, Fa, P

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cemiplimab-rwlc Libtayo [®] Regeneron Pharmaceuticals	Anti-neoplastic agent; Anti-PD-1 mAB	Cutaneous squamous cell carcinoma	IV	Infusion related reaction, Embryo-Fetal toxicity, Immune mediated pneumonitis, colitis, hepatitis, endocrinopathies	P, B
cenegermin-bkbj Oxervate [™] Dompé farmaceutici S.p.A.	Recombinant Human Nerve Growth factor	Neurotrophic Keratitis	Opth	Remove contact lens before inserting and wait 15 minutes before reinserting	Fi, O, Fa, B, P
dacomitinib Vizimpro [®] Pfizer	Antineoplastic agent; EGFR inhibitor, Tyrosine kinase inhibitor	Metastatic non-small-cell lung cancer	PO	Dermatologic effects, GI toxicity, pulmonary toxicity	P, O
doravirine Pifeltro [™] Merck Sharpe and Dohme	Anti-retroviral; (non-nucleoside reverse transcriptase inhibitor (NNRTI)	HIV-1 treatment	PO	Immune Reconstitution Syndrome	S
duvelisib Copiktra [™] Verastem Oncology	Antineoplastic agent; Phosphatidylinositol 3-Kinase Inhibitor	Relapsed or refractory chronic lymphocytic leukemia, Small lymphocytic lymphoma and Follicular lymphoma	PO	Hepatotoxicity, Neutropenia, Embryo-Fetal toxicity REMS: mitigate the risks of fatal/serious toxicities including infections, diarrhea, or colitis, cutaneous reactions, and pneumonitis	O, Fa, P, A
elagolix Orilissa [™] AbbVie Inc.	Gonadotropin Releasing Hormone Antagonist	Endometriosis	PO	Bone loss, Reduced ability to recognize pregnancy, Suicidal ideation, Elevated hepatic transaminases	Fi, P

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elapegamase- IvI Revcovi™ Leadiant Biosciences	Enzyme; recombinant adenosine deaminase	Adenosine deaminase-severe combined immunodeficiency	IM	Antibody formation	P, O
emapalumab-lzsg Gamifant™ Novimmune SA	Interferon gamma blocking mAb	Primary hemophagocytic lympho- histiocytosis	IV	Infections Do not administer live vaccines Infusion-related reactions	Fi, O, B, P
encorafenib Braftovi™ Array Biopharma	Antineoplastic agent; BRAF Kinase Inhibitor	Unresectable or metastatic melanoma	PO	New primary malignancy, Tumor promotion Hemorrhage Uveitis QT Prolongation Embryo-fetal toxicity	O
eravacycline Xerava™ Tetraphase Pharmaceuticals	Antibiotic; Tetracycline derivative	Complicated intra- abdominal infections	IV	Anaphylactic reactions, Tetracycline-class ADRs.	P
erenumab-aooe Aimovig™ Amgen/Novartis	Calcitonin gene- related peptide receptor antagonist Human mAb	Preventative treatment for migraines	SQ	Packaging may contain latex	Fi
fish oil triglycerides Omegaven Fresenius Kabi	Caloric agent (Fish Oil emulsion)	Essential fatty acids for parenteral nutrition- associated cholestasis in pediatric patients	IV	Risk of death in preterm infants, HSR, Risk of infections, Fat overload syndrome, Refeeding syndrome, & triglyceridemia, Aluminum toxicity	O, Fa, P
fosnetupitant / palonosetron Akynzeo® Helsinn	Serotonin 5-HT ₃ antagonist/ Substance P/NK-1 antagonist	Prevention of acute and delayed N/V in cancer chemotherapy	PO/ IV	HSR, Serotonin syndrome	S

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fostamatinib Tavalisse™ Rigel Pharmaceuticals	Spleen Tyrosine Kinase Inhibitor	Thrombocytopenia	PO	GI toxicity, Neutropenia, Hepatotoxicity, Hypertension	S, O
fremanezumab-vfrm Ajovy™ Teva	Calcitonin gene-related peptide receptor antagonist, human mAb	Migraine prophylaxis	SQ	HSR,	
galcanezumab-gnlm Emgality™ Eli Lilly and Co	Calcitonin gene-related peptide receptor antagonist Human mAB	Preventive treatment for migraine	SQ	HSR	S
gilteritinib Xospata® Astellas	Antineoplastic agent; FLT3 inhibitor, Tyrosine Kinase inhibitor	Acute myeloid leukemia	PO	GI toxicity, Hypersensitivity, Pancreatitis, QT prolongation	P, O
glasdegib Daurismo™ Pfizer Oncology	Hedgehog pathway inhibitor	Acute myeloid leukemia or high risk myelo-dysplastic syndrome	PO	BBW: Embryo-Fetal toxicity, Do not donate blood, QTc prolongation	O, P
ibalizumab-uiyk Trogarzo™ TaiMed Biologics	Anti-CD4 mAB, antiretroviral, post attachment inhibitor	HIV-1 infection	IV	Infusion related reactions, Immune reconstitution inflammatory syndrome	P, O
inotersen Tegsedi™ Ionis Pharmaceuticals	Antisense oligonucleotide	Polyneuropathy of hereditary transthyretin-mediated amyloidosis	SQ	BBW: Glomerulonephritis and Thrombocytopenia	P, O
ivosidenib Tibsovo® Agiros Pharmaceuticals	Anti-neoplastic agent; IDH1	Relapsed or refractory acute myeloid leukemia	PO	BBW: Differentiation syndrome, QT prolongation, GI toxicity	P, O
lanadelumab Takhzyro™ Shire Pharmaceuticals	mAB; Kallikrein inhibitor	Type I and II hereditary angioedema	SQ	HSR	P, O

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larotrectinib Vitrakvi® Loxo Oncology	Anti-neoplastic agent; Tropomyosin Receptor, Tropomyosin Receptor Kinase (TRK) inhibitor	Metastatic solid tumors with NTRK-fusion proteins	PO	Bone marrow suppression, GI toxicity, Hepatotoxicity, Neurotoxicity	P, O
lofexidine Lucemyra™ US WorldMeds	Alpha-2-Adrenergic agonist	Opioid withdrawal	PO	HTN, Bradycardia QTc prolongation, Increased risk of opioid overdose	Fi, Fa, P
lorlatinib Lorbrena® Pfizer	Anti-neoplastic agent; anaplastic lymphoma kinase inhibitor, tyrosine kinase inhibitor	(ALK-positive) non-small cell lung cancer	PO	CNS Effects, Risk of serious hepatotoxicity with CYP3A inducers, AV block, Embryo-Fetal toxicity	O, B, P, A
lusutrombopag Mulpleta® Quotient Sciences, Philadelphia	Colony Stimulating Factor, Thrombopoietic agent	Chronic Liver disease associated thrombocytopenia	PO	Thrombotic/thromboembolic complications	Fa, P
lutetium Lu 177 dotatate Lutathera® Advanced Accelerator Applications, S.r.l.	Radio-pharmaceutical (somatostatin analogue)	Gastro-pancreatic neuroendocrine tumors	IV	Myelosuppression, Secondary, myelodysplastic syndrome, Renal/hepatic toxicity, Neuroendocrine hormonal crisis	Fi, B,FA,
migalastat Galafold™ Amicus Therapeutics	alpha-galactosidase A pharmacologic chaperone	Fabry disease	PO	None	Fi,O,Fa,P,A
mogamulizumab-kpkc Poteligeo® Kyowa Kirin	Hematology	Relapsed or refractory mycosis, fungoides, or Sézary syndrome	IV	Autoimmune toxicity, Bone marrow suppression, Life-threatening infection	P, O
moxetumomab pasudotox-tdfk Lumoxiti™ AstraZeneca	Anti-neoplastic agent, anti-CD22	Hairy cell leukemia (relapsed or refractory)	IV	BBW: Capillary Leak syndrome, Hemolytic uremic syndrome	O, Fa, P

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moxidectin (no Brand name) Medicines Development for Global Health	Anthelmintic	Onchocerciasis	PO	Orthostatic hypotension Edema and worsening onchodermatitis	O, P
omadacycline Nuzyra™ Paratek Pharmaceuticals	Tetracycline antibiotic	Community acquired Pneumonia (CAP) Skin/Soft Tissue Infection (SSTI)	IV/ PO	Tooth discoloration, Enamel hypoplasia Inhibition of bone growth CDAD	Fa, P
patisiran Onpattro™ Alnylan Pharmaceuticals	Small interfering RNA (siRNAs)	Polyneuropathy of hereditary transthyretin-mediated amyloidosis	IV	Infusion-related reactions, Reduced serum Vitamin A levels	Fi, O, Fa, B, P
pegvaliase-pqpz Palynziq™ BioMarin Pharmaceutical Inc	Phenylalanine Ammonia Lyase Enzyme	Phenylketonuria (PKU)	SQ	BBW: Anaphylaxis REMS: mitigate the risk of anaphylaxis	Fi, O, Fa P
plazomicin Zemdri™ Achaogen	Aminoglycoside antibiotic	Complicated urinary tract infections	IV	BBW: nephrotoxicity, ototoxicity, neuromuscular blockade, contraindication in pregnancy	P
prucalopride Motegrity™ Shire US	Serotonin 5-HT-4 receptor agonist	Chronic idiopathic constipation	PO	Suicidal ideation and behavior	S
ravulizumab-cwvz Ultomiris™ Alexion Pharmaceuticals	mAB; Complement inhibitor	Paroxysmal nocturnal hemoglobinuria	IV	BBW: serious meningococcal infection REMS: mitigate the occurrence and morbidity associated with meningococcal infections	O

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revefenacin Yupelri™ Theravance Biopharma	Anticholinergic agent; long acting	Chronic obstructive pulmonary disease	Inh	Bronchospasm, CNS effects, hypersensitivity	N/A
rifamycin SV MMX Aemcolo™ Cosmo Pharmaceuticals	Antibiotic; Ansamycin class	Traveler's diarrhea caused by non-invasive strains of <i>E. coli</i>	PO	Risk of persistent or worsening diarrhea complicated by fever and/or bloody stool, CDAD	Fa,P
sarecycline Seysara™ Paratek Pharmaceuticals	Antibiotic; Tetracycline derivative	Severe acne vulgaris	PO	CNS effects, intracranial hypertension, photosensitivity, superinfection	S
segesterone acetate/ethinyl estradiol Annovera™ Population Council	Progestin/estrogen combination hormonal contraceptive	Vaginal ring to prevent pregnancy	Vag	Thrombotic disorders Liver disease HTN Headache Carbohydrate and lipid metabolic effects	S
sodium zirconium cyclosilicate Lokelma™ AstraZeneca Pharmaceuticals	Potassium Binder	Hyperkalemia	PO	Edema, GI motility concerns	S
stiripentol Diacomit® Biocodex	Anticonvulsant	Dravet Syndrome	PO	Somnolence Decreased appetite and decreased weight gain Neutropenia Suicidal behavior/ideation	O,P
tafenoquine Krintafel GlaxoSmithKline	Anti-malarial agent; Aminoquinolone	Malaria, Prevention of relapse by <i>Plasmodium vivax</i>	PO	Hemolytic anemia, G6PD deficiency in pregnancy, Methemoglobinemia, HSR, Psychiatric effects	S

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tagraxofusp-erzs Elzonris™ Stemline Therapeutics	Antineoplastic agent; Anti-CD123	Blastic plasmacytoid dendritic cell neoplasm	IV	BBW: Capillary leak syndrome	Fi,O,B,P
talazoparib Talzenna® Pfizer	Antineoplastic agent; PARP inhibitor	Metastatic breast cancer	PO	Bone marrow suppression, GI toxicity, secondary malignancy	P
tecovirimat Tpoxx® Siga Technologies	Antiviral agent	Smallpox	PO	Co-administration with repaglinide may cause hypoglycemia	P, O
tezacaftor/ ivacaftor Symdeko® Vertex	Cystic Fibrosis Transmembrane Conductance Regulator Corrector /Potentiator	Cystic fibrosis	PO	Cataracts, CNS effects, Hepatic effects	P, O
tildrakizumab-asmn Ilumya™ Merck Sharp and Dohme	Antineoplastic agent; interleukin-23 antagonist	Plaque psoriasis	SQ	HSR, Increased risk of infections	S

Intravenous (IV) Subcutaneous (SQ) Intramuscular (IM) Oral (PO) Inhaled (Inh) Ophthalmic (Opht)
Vaginal (Vag)

*Review Classifications

Fa= fast track

Fi = first-in-class

A = accelerated approval

B = breakthrough

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

†Warnings

BBW: Black Box Warning

HSR: Hypersensitivity Reactions

REMS: Risk Evaluation and Mitigation Strategies

Summary:

Each year, the FDA's Center for Drug Evaluation (CDER) reviews and approves a variety of novel drugs, those which serve previously unmet needs or help advance patient treatments. In 2018, the FDA's Center for Drug Evaluation (CDER) approved 59 novel drugs, which surpassed the agency's previous record of 53 approvals in 1996 and is considerably more than the 46 new drugs approved in 2017.² These drugs were approved as either new molecular entities, new

drug applications, or as new therapeutic biologics.¹ Previous years' approved drugs averaged 33 novel drug approvals per year. The new drugs will improve the quality of life and may even improve chances of surviving in a wide range of illnesses including: infectious disease, neurological disorders, heart, lung and circulatory diseases, women's health and cancer and blood disorders. This group of approvals bring in the first drug ever to treat smallpox, tecovirimat (*Tpoxx*[®]), the first of a new class of drugs to treat patients with HIV-1 infection who have failed other therapies, ibalizumab-uiyk (*Trogarzo*[™]), and a new single dose treatment for influenza, baloxavir marboxil (*Xofluza*[™]).

There were also drugs approved for new advances in certain patients with breast, lung, and thyroid cancers, as well as new drug therapies to treat blood cancers and blood disorders.

Other key findings in the class of 2018 include:³

- 3 of 59 (5.1%) drugs were REMS approved, compared to 1 of 46 (2.2%) in 2017.
- 10 of 59 drugs (16.9%) of drugs received BBWs, compared to 14 of 46 drugs (30.4%) in 2017, and 6 of 22 (27%) in 2016.
- Cancer and blood disorder drugs were most represented accounting for 36% (21 out of 59) of approved drugs
- The second most represented therapeutic group was infectious diseases 19% (11 out of 59)
- 19 of the 59 drugs were approved in 2018 (23%) as first-in-class, which indicates the drug's potential for a strong, positive impact on the health of the American people
- 34 of the 59 drugs approved in 2018 (58%) were approved to treat rare or "orphan" diseases (few or no drugs available to treat a condition). This compared to 21 of 45 drugs (47%) in 2015, 9 of 22 drugs (41%) in 2016, and 18 of 46 drugs (39%) in 2017.^{2,4,5}
- 24 of the 59 drugs (41%) were designated as Fast Track, which speeds up new drug development and review.
- 14 of the 59 novel drugs (24%) are considered breakthrough therapy for serious or life-threatening diseases for which there is unmet medical need.
- 42 of the 59 drugs (71%) were reviewed in an expedited time line, categorized as priority review. These drugs were reviewed within 8 months compared to the standard 12 months.

From 2011 - 2017, 205 out of 250 (82%) novel drugs were approved on the first cycle.³ This means that approval came without the CDER requiring further information from drug developers regarding submitted applications. When further information is required, drug approval can be delayed significantly. In 2018, 56 of the 59 novel drugs (95%) were first cycle approved.³ This was a notable increase from the 85% first cycle approval rate in 2017. The overall high proportion of first cycle approvals over the past nine years suggests that the FDA, along with drug developers, are committed to increasing the efficiency in drug approval to meet patient needs, while continuing to maintain high standards for safety.

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The last “dose” ...

“Nothing is impossible, the word itself says, “I’m possible.”

-Audrey Hepburn, Actress

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