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Guest Editor: J. Luke Britton, Pharm.D. Candidate 2018

New Drugs Approved in 2017

Generic Name Trade Name **Manufacturer**	**Category**	**Use**	**Route**	**Warnings˚**	**Review Classification***
abaloparatide Tymlos™ **Radius Health Inc.**	Parathyroid hormone analog	Osteoporosis	SQ	**BBW:** Osteosarcoma **BBW:** Limit use to 2 years Hypercalcemia Orthostatic hypotension	S
abemaciclib Verzenio™ **Eli Lilly & Co.**	Cyclin-dependent kinase inhibitor, antineoplastic agent	Breast cancer	PO	Fetal harm Hepatotoxicity Neutropenia Severe diarrhea Venous thromboembolic events	P
acalabrutinib Calquence® **AstraZeneca**	Tyrosine kinase inhibitor, antineoplastic agent	Mantle cell lymphoma	PO	Atrial fibrillation/flutter Bleeding events Bone marrow suppression CYP3A4 interactions	P, O

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				Opportunistic infection Secondary carcinoma	
angiotensin II Giapreza™ **La Jolla Pharmaceutical Co.**	Vasoactive agent	Septic or other distributive shock	IV	Venous thromboembolic events	P
avelumab Bavencio® **EMD Serono Inc.**	Anti-PD-L1 monoclonal antibody	Merkel cell carcinoma Urothelial carcinoma	IV	Fetal harm Immune-mediated reactions	N/A, O
benralizumab Fasenra™ **AstraZeneca**	Interleukin-5 receptor antagonist, monoclonal antibody	Asthma	SQ	Helminth infection Hypersensitivity reaction	N/A
benznidazole [approved with no trade name] **Chemo Research SL**	Nitroimidazole, antiprotozoal	Chagas Disease	PO	Bone marrow suppression Disulfiram reaction Fetal harm Genotoxicity Peripheral neuropathy Severe skin reactions	P, O
betrixaban Bevyxxa™ **Portola Pharms Inc.**	Factor Xa Inhibitor, anticoagulant	VTE Prophylaxis	PO	**BBW:** Epidural or spinal hematomas Increased bleed risk Renal impairment	P
brigatinib Alunbrig™ **Ariad**	Anaplastic lymphoma kinase inhibitor	Non-small cell lung cancer	PO	Avoid strong CYP3A4 interactions Bradycardia	P, O

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				Fetal harm Hyperglycemia Hypertension Respiratory disease Visual disturbance	
brodalumab Siliq™ **Valeant Luxembourg**	Anti-interleukin-17 receptor monoclonal antibody	Plaque psoriasis	SQ	**BBW:** Suicidal ideation **REMS:** Suicidal behavior Avoid live vaccines Serious infections	N/A
cerliponase alfa Brineura™ **Biomarin Pharm**	Hydrolytic lysosomal N-terminal tripeptidyl peptidase	Neuronal ceroid lipofuscinosis type 2	IV	Anaphylaxis Cardiovascular abnormalities Device-related infection	N/A, O
copanlisib Aliqopa™ **Bayer Healthcare**	Phosphatidylinositol 3-kinase inhibitor, antineoplastic	Follicular lymphoma	IV	Avoid strong CYP3A4 inhibitors Cutaneous reactions Fetal harm Hyperglycemia Hypertension Neutropenia Secondary infection	P, O
delafloxacin Baxdela™	Fluoroquinolone antibiotic	SSTI	PO/IV	**BBW:** Tendon rupture	P

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Melinta Therapeutics				**BBW:** Myasthenia gravis Neuropathy Superinfection	
deflazacort Emflaza® **PTC Therap**	Corticosteroid	Duchenne muscular dystrophy	PO	Avoid live vaccines Endocrine abnormalities Immune-mediated reactions Psychiatric dysfunction Renal impairment Serious cardiovascular events	P, O
deutetrabenazine Austedo™ **Teva Branded Pharm**	Vesicular monoamine transporter 2 (VMAT2) inhibitor	Chorea w/ Huntington's Disease Tardive dyskinesia	PO	**BBW:** Suicidality, depression Avoid MAOIs Hepatic impairment Hyperprolactinemia Neurological complications Ophthalmic risk QT prolongation	S, O
dupilumab Dupixent® **Regeneron Pharmaceuticals**	Interleukin-4 receptor antagonist, monoclonal antibody	Atopic dermatitis	SQ	Hypersensitivity Ophthalmic reactions Respiratory reactions	N/A

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durvalumab Imfinzi™ **Astrazeneca UK LTD**	Anti-PD-L1 monoclonal antibody	Urothelial carcinoma, Non-small cell lung cancer (off-label)	IV	Fetal harm Immune-mediated infections Infusion site reactions	N/A
edaravone Radicava® **Mitsubishi Tanabe**	Free radical scavenger	Amyotrophic lateral sclerosis (ALS)	IV	Anaphylaxis	S, O
emicizumab Hemlibra® **Genentech Inc.**	Antihemophilic, monoclonal antibody	Hemophilia A, prophylaxis	SQ	**BBW:** Thrombotic microangiopathy and thrombotic events	N/A, O
enasidenib Idhifa® **Celgene Corp.**	IDH2 inhibitor, antineoplastic agent	Acute myeloid leukemia	PO	**BBW:** Differentiation syndrome Fetal harm Leukocytosis Tumor lysis syndrome	P, O
ertugliflozin Steglatro™ **Merck Sharp & Dohme Corp.**	Antidiabetic agent, SGLT-2 inhibitor	Type 2 diabetes mellitus	PO	Genital mycosis Hypotension Increased LDL-C Ketoacidosis Limb amputation Renal impairment Urinary tract infection	S
etelcalcetide Parsabiv™ **Kai Pharms Inc.**	Calcimimetic	Secondary hyperpara-thyroidism	IV	GI bleed Heart dysfunction Hypocalcemia	S

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				QT prolongation Seizure risk	
glecaprevir/ pibrentasvir Mavyret™ **Abbvie Inc.**	Protease inhibitor	Hepatitis C	PO	**BBW:** Hepatitis B reactivation Avoid CYP3A4 interactions Hepatic impairment	S
guselkumab Tremfya™ **Janssen Biotech**	Interleukin-23 inhibitor, monoclonal antibody	Plaque psoriasis	SQ	Avoid live vaccines Superinfection TB reactivation	N/A
inotuzumab ozogamicin Besponsa® **Wyeth Pharms Inc.**	Anti-CD22, antineoplastic agent	Acute lymphoblastic leukemia	IV	**BBW:** Hepatotoxicity **BBW:** Post-stem cell transplant mortality Fetal harm Hemorrhage Hepatic disease Infusion site reactions Myelosuppression QT Prolongation Superinfection	N/A, O
latanoprostene bunod Vyzulta™ **Bausch and Lomb**	Antiglaucoma, prostaglandin	Elevated intraocular pressure	Opht	Bacterial keratitis Increased pigmentation of eye and other tissues Intraocular inflammation	S

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				Macular edema	
letermovir Prevymis™ **Merck Sharp Dohme**	Antiviral agent	Hematopoietic stem cell transplant, cytomegalovi-rus prophylaxis	PO	Hepatic impairment Moderate-strong CYP3A4 interactions Renal impairment	P, O
macimorelen acetate Macrilen™ **Aeterna Zentaris**	Growth hormone receptor antagonist	Growth hormone deficiency	PO	Avoid strong CYP3A4 inducers QT prolongation	S, O
meropenem/ vaborbactam Vabomere™ **Rempex Pharms**	Carbapenem antibiotic/beta-lactamase inhibitor	Urinary tract infection	IV	Beta-lactam hypersensitivity Neurological impairment Renal impairment Seizures Superinfection Thrombocytopenia	P
midostaurin Rydapt® **Novartis Pharms Corp**	FLT3 tyrosine kinase inhibitor, antineoplastic agent	Acute myeloid leukemia Mast cell leukemia Systemic mastocytosis	PO	Fetal harm QT prolongation Respiratory disease	P, O
naldemedine Symproic® **Shionogi Inc.**	Opioid antagonist	Opioid-induced constipation	PO	GI perforation Hepatic impairment Opioid withdrawal	S
neratinib maleate Nerlynx™ **Puma Biotech**	Anti-HER2 tyrosine kinase inhibitor	HER2-positive breast cancer	PO	Fetal harm GI toxicity Hepatotoxicity	S

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netarsudil Rhopressa® **Aerie Pharmaceuticals Inc.**	Rho kinase inhibitor	Elevated intraocular pressure	Opht	Bacterial keratitis Conjunctival hemorrhage	S
niraparib Zejula® **Tesaro Inc.**	PARP inhibitor, antineoplastic	Peritoneal cancer	PO	Fetal harm Hypertensive crisis Myelosuppression	P, O
ocrelizumab Ocrevus™ **Genentech Inc.**	Anti-CD20 monoclonal antibody	Multiple sclerosis	IV	Avoid live vaccines Hepatitis B reactivation Infusion site reactions Malignancy Progressive Multifocal Leuko-encephalopathy (PML) Superinfection	N/A
ozenoxacin Xepi™ **Ferrer Internacional**	Quinolone antibiotic	Impetigo	Top	Mycosis	S
plecanatide Trulance® **Syngergy Pharms**	Guanylate cyclase-C (GC-C) agonist	Chronic idiopathic constipation (CIC)	PO	**BBW:** Pediatric dehydration Severe diarrhea	S
ribociclib Kisqali® **Novartis Pharms Corp.**	Cyclin-dependent kinas inhibitor, antineoplastic	Breast cancer	PO	Avoid strong CYP3A4 inhibitors Bone marrow suppression Fetal harm QT prolongation	P
safinamide Xadago® **US Worldmeds LLC**	MAO type B inhibitor	Parkinson's Disease	PO	Hypertensive crisis Neurological	S

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				abnormalities Ophthalmic abnormalities Psychosis Serotonin syndrome	
sarilumab Kevzara® **Sanofi Synthelabo**	Interleukin-6 receptor antagonist, monoclonal antibody	Rheumatoid arthritis	SQ	**BBW:** Avoid immuno-suppressants **BBW:** Opportunistic infection **BBW:** TB infection Avoid live vaccines Dyslipidemia Fetal harm GI perforation Hepatotoxicity Neutropenia	N/A
secnidazole Solosec™ **Lupin**	Nitroimidazole, antiprotozoal	Bacterial vaginosis	PO	Superinfection	P
semaglutide Ozempic® **Novo Nordisk Inc.**	Antidiabetic agent, GLP-1 receptor antagonist	Type 2 diabetes mellitus	SQ	**BBW:** Medullary thyroid carcinoma Anaphylaxis with other GLP-1 receptor agonists Diabetic retinopathy Hypoglycemia Pancreatitis	S

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				Renal impairment	
sofosbuvir/velpatasvir/ voxilaprevir Vosevi® **Gilead Sciences Inc.**	NS5B polymerase inhibitor/NS5A inhibitor/ NS3/4A protease inhibitor	Hepatitis C	PO	**BBW:** Hepatitis B reactivation Avoid P-gp and CYP interactions Bradycardia Cardiac arrest Hepatic impairment	P
telotristat ethyl Xermelo™ **Lexicon Pharms Inc.**	Tryptophan hydroxylase inhibitor	Carcinoid syndrome diarrhea	PO	Intestinal perforation	P, O
valbenazine Ingrezza® **Neurocrine**	Vesicular monoamine transporter 2 (VMAT2) inhibitor	Tardive dyskinesia	PO	Avoid CYP2D6, 3A4 inhibitors QT interval prolongation Somnolence	P
vestronidase alfa-vjbk Mepsevii™ **Ultragenyx Pharm Inc.**	Enzyme	Mucopolysacch -aridosis VII	IV	**BBW:** anaphylaxis	N/A, O

Intravenous (IV) Subcutaneous (SQ) Intrathecal (IT) Oral (PO) Topical (Top) Ophthalmic (Opht)

*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

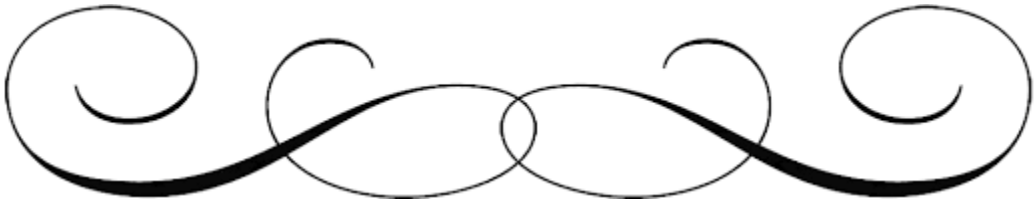
O = orphan drug

N/A = Not Applicable for drug classification

*Warnings

BBW (Black Box Warning)

REMS (Risk Evaluation and Mitigation Strategy)



Summary:

The FDA's Center for Drug Evaluation and Research (CDER) is responsible for evaluating and approving all new drug products for US market. New Molecular Entities, novel drugs with active ingredients brand new to FDA evaluation, seek approval for innovative use in meeting unfulfilled needs or providing valuable alternatives to current therapy. In 2017, 46 novel drugs (or NMEs) were approved. This is a rebound to previous rates following only 22 novel drugs being approved in 2016. This rises back above the average of 31 new drugs approved annually in the last decade. This year was comparable to 45 novel drugs in 2015 and 41 novel drugs in 2014. Novel drug approval in 2017 broadened healthcare's arsenal in meeting the needs of the general public. Novel drug approvals provided new treatments for conditions such as the first therapy for Chagas Disease, an antiviral for cytomegalovirus prevention, and two treatments for Tardive Dyskinesia. Additionally, new therapies were approved for incorporation into established treatment schemes of disease states such as osteoporosis, Hepatitis C, and Type 2 diabetes mellitus. Finally, 12 novel therapies were approved for neoplastic conditions ranging from breast cancer to Merkel cell carcinoma.

Other key findings:

- Only eighteen of the 2017 novel drugs (39%), compared to 73% in 2016, received a fully expedited approval to bring them to the market as quickly as possible.

- Fifteen of the 46 novel drugs approved (33%) were identified as First-in-Class, having a mechanism different from any existing therapies.

- Eighteen (39%) were approved to treat rare or "orphan" diseases, affecting 200,000 or fewer Americans who otherwise would have limited-to-no available treatment options.

- Fourteen (30%) of the novel agents had an associated Black Box Warning.
    - BBWs for Hepatitis B reactivation and suicidal ideation were most common at two drugs with each.

- Thirteen (28%) carried significant risk for fetal harm.
    - All but two of these agents were approved for a neoplastic condition.

- Nine (20%) of the novel agents approved were monoclonal antibodies, expanding the field of novel biologic therapies in modern medicine.

- Only one novel therapy was approved with REMS.
    - Siliq™ (brodalumab), a SQ injection for plaque psoriasis, has a REMS program to educate patients and prescribers about the significant risk of suicidal ideation associated with therapy.

Improvements are continually being made to the process of drug approval. Approval during the "first cycle" of review, meaning novel drugs approved without requests for additional information leading to delayed approval and a secondary review cycle, decreased to 85% in 2017 from an impressive 95% the previous year. Additionally, 2017 saw an increase in foreign drug approval with 78% of drugs being approved in the United States before being approved in other countries, compared to 86% in 2016.

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The last "dose" …

"Anything lost can be found . . . except time. Use it wisely."

-Gene Chizik [Auburn Football Coach, 2009-2012]

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