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New Drugs Approved in 2016

Generic Name Trade Name Manufacturer	Category	Use	Route	Warnings°	Review Classification*
atezolizumab Tecentriq® **Genentech**	Antineoplastic agent	Treatment of urothelial carcinoma	IV	Adrenal insufficient Diabetes mellitus GI toxicity Hepatotoxicity Infection Pulmonary toxicity Thyroid disorder	N/A
bezlotoxumab Zinplava™ **Merck Sharp & Dohme Corp.**	Monoclonal antibody	To reduce the recurrence of Clostridium difficile infection; in patients 18 years or older	IV	Heart Failure	N/A
brivaracetam Briviact® **UCB**	Anticonvulsant	Treatment of partial onset seizure; in patients 16 years and older with epilepsy	PO IV	CNS depression Effects on blood Hypersensitivity Psychosis Suicidal ideation Hepatic impairment Renal impairment	S

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crisaborole Eucrisa™ **Pfizer**	Phosphodiesterase-4 (PDE-4) enzyme inhibitor	Treat mild to moderate eczema (atopic dermatitis); in patients two years of age and older	Top	Hypersensitivity reactions	S
daclizumab Zinbryta™ **Biogen**	Immunosuppressant; Interleukin-2 inhibitor; monoclonal antibody	Treatment of multiple sclerosis	SQ	BBW: Hypersensitivity Hepatotoxicity Contraindicated in hepatic impairment Hypersensitivity reactions Infections Depression and suicide REMS	N/A
defibrotide sodium Defitelio® **Jazz Pharms Inc.**	Thrombolytic	Treatment of adults and children who develop hepatic veno-occlusive disease with renal or pulmonary dysfunction following hematopoietic stem cell transplantation	IV	Hemorrhage Hypersensitivity reactions	P, O
elbasvir and grazoprevir Zepatier™ **Merck Sharp & Dohme Corp.**	Antihepaciviral	Treatment of chronic hepatitis C virus (HCV) genotypes 1 and 4 infections in adults	PO	Contraindicated in hepatic impairment ALT elevations	P

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eteplirsen Exondys 51™ **Sarepta Therapeutics**	Antisense oligonucleotide	Treatment of Duchenne muscular dystrophy (DMD)	IV	None	P, O
fluciclovine F 18 Axumin™ **Blue Earth Diagnostics**	Diagnostic agent	Diagnostic imaging agent to detect recurrent prostate cancer	IV	Radiation risk	P
gallium Ga 68 dotatate NETSPOT™ **Advanced Accelerator Applications**	Diagnostic agent	Diagnostic imaging agent to detect rare neuroendocrine tumors	IV	Radiation risk	P, O
ixekizumab Taltz® **Lilly**	Antipsoriatic	Treatment of moderate-to-severe plaque psoriasis; adult	SQ	Infections Tuberculosis Hypersensitivity Inflammatory Bowel Disease	N/A
lifitegrast ophthalmic solution Xiidra® **Shire**	Lymphocyte function-associated antigen-1 (LFA-1) antagonist	Treatment for dry eye syndrome	Ophth	Contact lens wearers; remove lens prior to administration	P
lixisenatide Adlyxin™ **Sanofi-Aventis**	Glucagon-like peptide-1 (GLP-1) agonist	Type 2 diabetes mellitus	SQ	Anti-lixisenatide antibody formation Hypersensitivity Pancreatitis Gastroparesis Renal dosing adj.	S
nusinersen Spinraza™ **Biogen**	Antisense oligonucleotide	Spinal muscular atrophy	IT	Thrombocytopenia Coagulation abnormalities Renal toxicity	P, O

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obeticholic acid Ocaliva® **Intercept Pharmaceuticals**	Farnesoid X receptor (FXR) agonist	Primary biliary cholangitis (PBC)	PO	Hepatic effects (jaundice, worsening ascites, PBC flare) HDL-C reduction Severe pruritus	P, O
obiltoxaximab Anthim® **Elusys Therapeutics**	Antidote; monoclonal antibody	Anthrax, inhalation: Treatment and prophylaxis	IV	BBW: Hypersensitivity Anaphylaxis Pre-medicate with diphenhydramine	O
olaratumab Lartruvo™ **Eli Lilly**	Antineoplastic agent	Treatment of soft tissue sarcoma	IV	Infusion-related reactions (Pre-medicate with diphenhydramine and dexamethasone) Embryo-fetal toxicity	O
pimavanserin Nuplazid™ **Acadia Pharmaceuticals**	Atypical antipsychotic	Treatment for Parkinson disease psychosis	PO	BBW: Increased mortality in elderly with dementia-related psychosis QT prolongation	P
reslizumab Cinqair® **Teva Pharmaceuticals Industries**	Interleukin-5 antagonist; monoclonal antibody	Maintenance therapy for severe asthma	IV	BBW: Anaphylaxis Malignancy Helminth infection	P
rucaparib Rubraca™ **Clovis Oncology**	Poly (ADP-ribose) polymerase (PARP) inhibitor	Treatment for ovarian cancer, advanced	PO	Myelodysplastic syndrome/acute myeloid leukemia (MDS/AML) Embryo-fetal toxicity	P, O

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sofosbuvir and velpatasvir Epclusa® **Gilead Sciences**	Antihepaciviral	Treatment of chronic hepatitis C, genotypes 1-6	PO	Bradycardia	P
venetoclax Venclexta™ **AbbVie**	BCL-2 inhibitor	Treatment of chronic lymphocytic leukemia	PO	Tumor lysis syndrome Neutropenia Immunization (no live vaccines) Embryo-fetal toxicity	P, O

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

*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

Warnings˚

BBW (Black Box Warning)

REMS (Risk Evaluation and Mitigation Strategy)

Summary:

The FDA's Center for Drug Evaluation and Research (CDER) approves hundreds of new medications every year. Novel drugs (or New Molecular Entities) are a small subset of these approvals, often more innovative, serving unmet medical needs or otherwise advancing public health. In 2016, 22 novel drugs were approved, which is lower than the average of 30 new drugs approved annually in the last decade. This was substantially lower than the number of new drugs approved the previous two years, 45 novel drugs in 2015 and 41 novel drugs in 2014. Although the number approved was lower, the number of applications submitted for these drugs remained stable.

The quality of the approved 2016 novel drugs and the important new roles of these drugs to advance medical care is more important than the quantity. Novel approvals for 2016 included the first treatment for patients with spinal muscular atrophy, the first drug approved to treat Duchenne muscular dystrophy, a new drug to treat hallucinations and delusions in some people with Parkinson's disease, a new drug to treat patients with a rare chronic liver disease known as primary biliary cirrhosis, and two new treatments for patients with hepatitis C. Also included are new treatments for ovarian cancer, bladder cancer, soft tissue sarcoma, and chronic lymphocytic leukemia as well as new diagnostic agents for detecting certain forms of cancer.

Sixteen of the 2016 novel drugs (73%), compared to 60% in 2015, received an expedited approval to bring them to the market as quickly as possible. Eight of the 22 novel drugs approved (36%) were identified as First-in-Class, having a mechanism different from existing

therapies. Nine (41%) were approved to treat rare or “orphan” diseases, affecting 200,000 or fewer Americans who otherwise would have limited-to-no available treatment options.

The access to novel drugs has improved in 2016. The “first cycle” of review, meaning without requests for additional information delaying approval and therefore leading to a secondary review cycle, increased to 95% in 2016 from 87% the previous year. Additionally, 2016 showed an increase in the percentage of drugs approved in the United States before being approved in other countries, 86% compared to 64% in 2015.

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The last “dose” …

“There’s a way to do it better… find it.”

-Thomas Edison [American inventor, 1847-1931]

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