

April 24, 2018

COM-2018-007

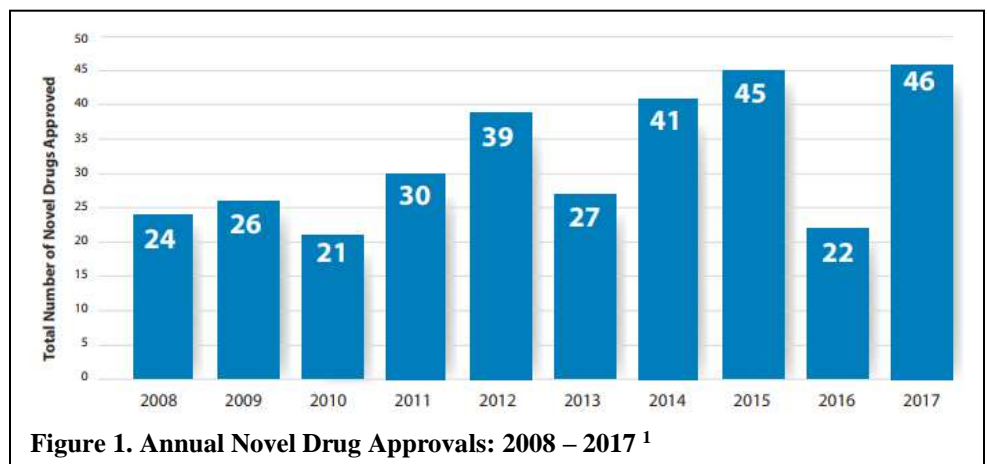
Dear provider of pharmaceutical services,

Novel drugs can represent important new therapies for advancing patient care. For this reason, it is important for pharmacists to keep up to date with new drug approvals. The following communication summarizes information regarding 2017 new drug approvals.

In 2017, the FDA approved a wide variety of drugs for the treatment of many different medical conditions (from rare disorders to common diseases), including: (1) novel drugs, (2) new and expanded uses for already FDA-approved drugs, (3) biosimilars, (4) new formulations or new manufacturers of already FDA-approved drugs, and (5) new dosage forms.

Within the last 10 years, an average of 31 novel drugs were per year (Figure 1). In 2017, a total of 46 novel drugs were approved. Cancer therapies and orphan-designated drugs led the path. In addition, 3 new gene therapies were approved under a separate category:

- Kymriah, for the treatment of B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.
- Yescarta, for the treatment of relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.
- Luxturna, for the treatment of confirmed biallelic RPE65 mutation-associated retinal dystrophy.



Impact of novel drug approvals

15 of the 46 novel drugs approved were first-in-class. These drugs have mechanisms of action different from those of existing therapies.

- Novel drugs approved in 2017 identified as first-in-class were: Besponsa, Brineura, Dupixent, Emflaza, Giapreza, Hemlibra, Idhifa, Macrilen, Mepsevii, Ocrevus, Prevymis, Radicava, Rhopressa, Rydapt, and Xermelo.

18 of the 46 novel drugs approved were drugs for rare or “orphan” diseases. Patients with rare or “orphan” diseases generally have few or no drugs alternatives to treat their conditions.

- Novel drugs approved with orphan drug designation were: Aliqopa, Alunbrig, Austedo, Bavencio, benznidazole, Besponsa, Brineura, Calquence, Emflaza, Hemlibra, Idhifa, Macrilen, Mepsevii, Prevymis, Radicava, Rydapt, Xermelo, and Zejula.

In addition to first-in-class and orphan designated drugs, several other novel drugs were approved for the first time in the United States. A list of all novel drugs approvals in 2017, and their FDA-approved use on approval date, is provided in Appendix 1.

New and expanded uses of already approved

After the FDA approves a new drug, it is common for a manufacturer to submit an application with new data that demonstrate safety and effectiveness of the same product for an additional purpose or for use in a different population of patients. A list of new and expanded uses of already approved drugs is provided in Appendix 2. Several already FDA-approved drugs also received expanded approval to include new populations of patients.

Biosimilars

Biosimilars expand treatment options and bring competition to the marketplace. 5 biosimilars were approved in 2017: (1) Cyltezo (adalimumab-adbm), biosimilar to Humira (adalimumab); (2) Ixifi (infliximab-qbtx), biosimilar to Remicade (infliximab); (3) Mvasi (bevacizumab-awwb), biosimilar to Avastin (bevacizumab); (4) Ogivri (trastuzumab-dkst) biosimilar to Herceptin (trastuzumab); and (5) Renflexis (infliximab-abda), also biosimilar to Remicade (infliximab).

New formulations

3 new formulations of already approved opioid drugs were approved: (1) Arymo ER (morphine sulfate extended-release tablets); (2) Roxybond (oxycodone immediate-release tablets); and (3) Vantrela ER (hydrocodone extended-release tablets). These new formulations have properties that are intended to deter abuse of these highly addictive medications.

Other new formulations and notable approvals include new combinations of active ingredients or new manufacturers of an already approved product.

For more information regarding new drug approvals for 2017, you can refer to the “2017 New Drug Therapy Approvals report from the FDA”, available at the following link: <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm537040.htm>. In addition, for more information about these drugs and for complete risk information, we encourage the review of the drugs’ approval letters and FDA-approved labeling at Drugs@FDA: FDA Approved Drug Products, available at the following link: <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>.

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Regards,

Pharmacy Department

Appendix 1. Novel Drug Approvals for 2017

Drug Name	Active Ingredient	FDA-approved use on approval date
Giapreza	angiotensin II	To increase blood pressure in adults with septic or other distributive shock
Macrilen	macimorelin acetate	For the diagnosis of adult growth hormone deficiency
Steglatro	ertugliflozin	To improve glycemic control in adults with type 2 diabetes mellitus
Rhopressa	netarsudil	To treat glaucoma or ocular hypertension
Xepi	ozenoxacin	To treat impetigo
Ozempic	semaglutide	To improve glycemic control in adults with type 2 diabetes mellitus
Hemlibra	emicizumab	To prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A who have developed antibodies called Factor VIII (FVIII) inhibitors.
Mepsevii	vestronidase alfa-vjvk	To treat pediatric and adult patients with an inherited metabolic condition called mucopolysaccharidosis type VII (MPS VII), also known as Sly syndrome.
Fasenra	benralizumab	For add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.
Prevymis	letermovir	To prevent infection after bone marrow transplant.
Vyzulta	latanoprostene bunod ophthalmic solution	To treat intraocular pressure in patients with open-angle glaucoma or ocular hypertension.
Calquence	acalabrutinib	To treat adults with mantle cell lymphoma
Verzenio	abemaciclib	To treat certain advanced or metastatic breast cancers
Solosec	secnidazole	To treat bacterial vaginosis.
Aliqopa	copanlisib	To treat adults with relapsed follicular lymphoma.
benznidazole	benznidazole	To treat children ages 2 to 12 years old with Chagas disease.
Vabomere	meropenem and vaborbactam	To treat adults with complicated urinary tract infections.
Besponsa	inotuzumab ozogamicin	To treat adults with relapsed or refractory acute lymphoblastic leukemia.
Mavyret	glecaprevir and pibrentasvir	To treat adults with chronic hepatitis C virus.
Idhifa	enasidenib	To treat relapsed or refractory acute myeloid leukemia.
Vosevi	sofosbuvir, velpatasvir and voxilaprevir	To treat adults with chronic hepatitis C virus.
Nerlynx	neratinib maleate	To reduce the risk of breast cancer returning.
Tremfya	guselkumab	For the treatment of adult patients with moderate-to-severe plaque psoriasis.
Bevyxxa	betrixaban	For the prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness.
Baxdela	delafloxacin	To treat patients with acute bacterial skin infections.
Kevzara	sarilumab	To treat adult rheumatoid arthritis.
Radicava	edaravone	To treat patients with amyotrophic lateral sclerosis (ALS).
Imfinzi	durvalumab	To treat patients with locally advanced or metastatic urothelial carcinoma.
Tymlos	abaloparatide	To treat osteoporosis in postmenopausal women at high risk of fracture or those who have failed other therapies.
Rydapt	midostaurin	To treat acute myeloid leukemia.
Alunbrig	brigatinib	To treat patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib.
Brineura	cerliponase alfa	To treat a specific form of Batten disease.
Ingrezza	valbenazine	To treat adults with tardive dyskinesia.
Austedo	deutetrabenazine	For the treatment of chorea associated with Huntington's disease.
Ocrevus	ocrelizumab	To treat patients with relapsing and primary progressive forms of multiple sclerosis.
Dupixent	dupilumab	To treat adults with moderate-to-severe eczema (atopic dermatitis).

Zejula	niraparib	For the maintenance treatment for recurrent epithelial ovarian, fallopian tube or primary peritoneal cancers.
Symproic	naldemedine	For the treatment of opioid-induced constipation.
Bavencio	avelumab	To treat metastatic Merkel cell carcinoma.
Xadago	safinamide	To treat Parkinson's disease.
Kisqali	ribociclib	To treat postmenopausal women with a type of advanced breast cancer.
Xermelo	telotristat ethyl	To treat carcinoid syndrome diarrhea.
Siliq	brodalumab	To treat adults with moderate-to-severe plaque psoriasis.
Emflaza	deflazacort	To treat patients age 5 years and older with Duchenne muscular dystrophy.
Parsabiv	etelcalcetide	To treat secondary hyperparathyroidism in adult patients with chronic kidney disease undergoing dialysis.
Trulance	plecanatide	To treat Chronic Idiopathic Constipation (CIC) in adult patients.

Appendix 2. New and Expanded Uses of Already FDA-Approved Drugs

Drug name	Original indication(s)	New indication(s)
Actemra (tocilizumab)	Rheumatoid arthritis (2010)	<ul style="list-style-type: none"> Giant cell arteritis Cytokine release syndrome
Dysport (abobotulinumtoxinA)	Cervical dystonia (torticollis) and wrinkles between the eyebrows (2009)	<ul style="list-style-type: none"> Muscle spasticity
Imbruvica (ibrutinib)	Mantle cell lymphoma (2013)	<ul style="list-style-type: none"> Chronic graft versus host disease (cGVHD) Marginal zone lymphoma
Nucala (mepolizumab)	Maintenance treatment of asthma (2015)	<ul style="list-style-type: none"> Eosinophilic granulomatosis with polyangiitis (EGPA)
Opdivo (nivolumab)	Unresectable or metastatic melanoma (2014)	<ul style="list-style-type: none"> Hepatocellular carcinoma Many other uses related to cancer therapy
Keytruda (pembrolizumab)	Advanced or unresectable melanoma (2014)	<ul style="list-style-type: none"> To treat patients whose cancers, have a specific biomarker Refractory classical Hodgkin lymphoma Gastric or gastro-esophageal junction adenocarcinoma
Revlimid (lenalidomide)	Transfusion dependent anemia (2005)	<ul style="list-style-type: none"> Multiple myeloma
Soliris (eculizumab)	To prevent the breakdown of red blood cells in people with paroxysmal nocturnal hemoglobinuria (2007)	<ul style="list-style-type: none"> Myasthenia gravis
Somatuline Depot (lanreotide)	Acromegalia (2007)	<ul style="list-style-type: none"> Carcinoid syndrome
Stelara (ustekinumab)	Plaque psoriasis (2006)	<ul style="list-style-type: none"> Crohn's disease
Stivarga (regorafenib)	Colorectal cancer (2012)	<ul style="list-style-type: none"> Hepatocellular carcinoma
Victoza (liraglutide)	Type 2 diabetes (2010)	<ul style="list-style-type: none"> Reducing risks of heart attack, stroke and cardiovascular deaths in patients with type 2 diabetes
Zelboraf (vemurafenib)	Melanoma with a specific genetic mutation	<ul style="list-style-type: none"> Erdheim-Chester Disease (ECD)

References:

- Center for Drug Evaluation and Research, Advancing health through innovation: 2017 New Drug Therapy Approvals. Available <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ReportsBudgets/UCM591976.pdf>
- New Drug Approvals. Drugs.com. Available at: <https://www.drugs.com/newdrugs.html>