

New Drugs Approvals by FDA in 2018

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Pharmaceutical industry is very challenging, and involves huge investments, strong regulations, and low output in terms of new drugs. FDA (U.S. Food and Drug Administration) provides scientific and regulatory advice needed to bring new therapies to market. Number of new drug approval for years 2013 - 2018 are shown in figure 1.

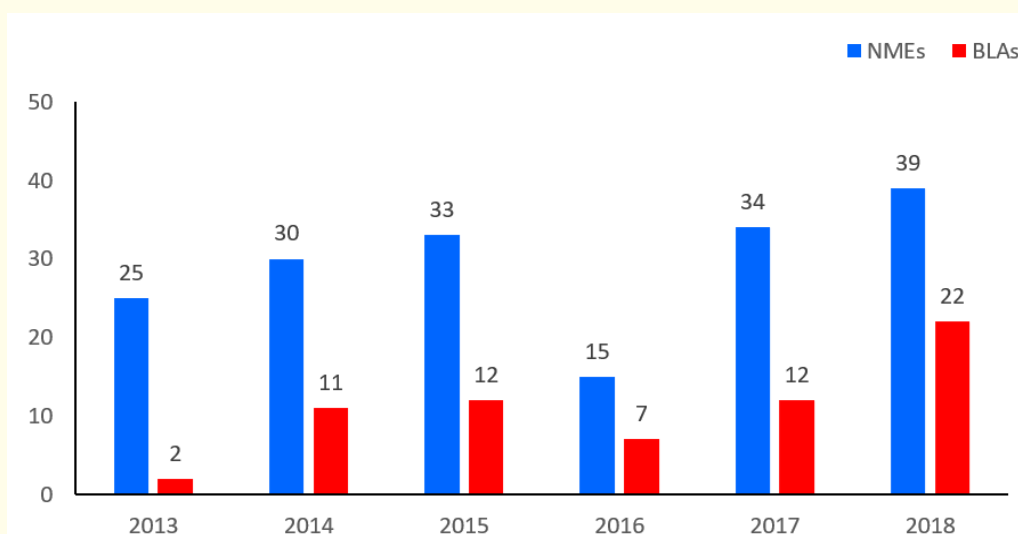


Figure 1: New drugs approved from 2013-2018 (NMEs: New Molecular Entities, BLAs: Biologics License Applications).

FDA has set a new record for new drug approvals in 2018 by approving 59 novel drugs and biologics, plus two recombinant therapies taking the total count to 61. Drugs approved in 2018 are listed in table 1. Number of new molecular entities (NMEs) and biologics approved by FDA exceeded its earlier record of 53 approvals in 1996. Number of new products approved by FDA in 2018 is nearly double its 10-year average of 33 approvals per year.

No.	Drug Name	Sponsor	Active Ingredient	Indication
1	Lutathera	Novartis	Lutetium Lu 177 dotatate	Gastroenteropancreatic neuroendocrine tumors
2	Biktarvy	Gilead	Bictegravir, embitcitabine, tenofovir alafenamide	HIV
3	Symdeko	Vertex	Tezacaftor; ivacaftor	Cystic fibrosis
4	Erleada	J&J	Apalutamide	Prostate cancer
5	Trogarzo	Taimed	Ibalizumab-uiyk	HIV
6	Ilumya	Sun	Tildrakizumab	Psoriasis
7	Tavalisse	Rigel	Fostamatinib	Chronic immune thrombocytopenia
8	Crysvita	Ultragenyx	Burosumab-twza	X-linked hypophosphatemia
9	Akynzeo	Helsinn	Fosnetupitant and palonosetron	nausea and vomiting associated with cancer chemotherapy
10	Andexxa	Portola	Andexanet alfa	Reversal of anticoagulation from FXa inhibitors
11	Lucemyra	US WorldMeds	Lofexidine hydrochloride	Opioid addiction
12	Aimovig	Amgen	Erenumab-aooe	Migraine
13	Lokelma	AstraZeneca	Sodium zirconium cyclosilicate	Hyperkalemia
14	Doptelet	Akarx	Avatrombopag	Thrombocytopenia
15	Palynziq	Biomarin	Pegvaliase-Pqpz	Phenylketonuria
16	Olumiant	Lilly	Baricitinib	Rheumatoid arthritis
17	Moxidectin	Med Devt for Gbl Hlth	Moxidectin	Onchocerciasis
18	Epidiolex	GW Research	Cannabidiol	Severe forms of epilepsy
19	Zemdri	Achaogen	Plazomicin	Complicated UTIs
20	Mektovi	Array	Binimetinib	Melanoma
21	Braftovi	Array	Encorafenib	Melanoma
22	TPOXX	Siga	Tecovirimat	Smallpox
23	Tibsovo	Agios	Ivosidenib	Leukemia
24	Krintafel	GSK	Tafenoquine	Malaria (<i>Plasmodium vivax</i>)
25	Orilissa	AbbVie	Elagolix sodium	Endometriosis
26	Omegaven	Frenesius Kabi	Fish oil triglycerides	Parenteral nutrition-associated cholestasis
27	Mulpleta	Shionogi	Lusutrombopag	Thrombocytopenia from chronic liver disease
28	Poteligeo	Kyowa Kirin	Mogamulizumab-kpkc	Non-Hodgkin lymphoma
29	Onpattro	Alnylam	Patisiran	Polyneuropathy of hereditary transthyretin-mediated amyloidosis
30	Annovera	Population Council	Segesterone acetate and ethinyl estradiol vaginal system	Female contraception
31	Galafold	Amicus	Migalastat	Fabry disease

32	Diacomit	Biocodex	Stiripentol	Seizures associated with Dravet syndrome
33	Oxervate	Dompe	Cenegermin-bkbj	Neurotrophic keratitis
34	Takhzyro	Shire	Lanadelumab	Hereditary angioedema
35	Xerava	Tetraphase	Eravacycline	Intra-abdominal infections
36	Jivi	Bayer	Blood clotting factor VIII	Hemophilia A
37	Pifeltro	Merck	Doravirine	HIV-1
38	Lumoxiti	AstraZeneca	Moxetumomab pasudotox-tdfk	Hairy cell leukemia
39	Ajovy	Teva	Fremanezumab-vfrm	Migraine
40	Copiktra	Verastem	Duvelisib	Leukemia (CLL), Lymphoma (FL)
41	Emgality	Lilly	Galcanzumab-gnlm	Migraine
42	Vizimpro	Pfizer	Dacomitinib	Lung cancer (NSCLC)
43	Libtayo	Regeneron	Cemiplimab-rwlc	Cutaneous squamous cell carcinoma
44	Seysara	Allergan	Sarecycline	Acne vulgaris
45	Nuzyra	Paratek	Omadacycline	Pneumonia, skin infections
46	Revcovi	Leadiant	Elapegademase-lvlr	Adenosine Deaminase-Severe Combined Immunodeficiency
47	Tegsedi	Ionis	Inotersen	Polyneuropathy of hereditary transthyretin-mediated amyloidosis
48	Talzenna	Pfizer	Talazoparib	Breast cancer (BRCA mutation)
49	Xofluza	Shionogi	Baloxavir marboxil	Influenza
50	Lorbrena	Pfizer	Lorlatinib	ALK-positive NSCLC
51	Yupelri	Theravance	Revefenacin	COPD
52	Aemcolo	Cosmo	Rifamycin	Traveler's diarrhea
53	Gamifant	Novimmune	Emapalumab-lzsg	Hemophagocytic lymphohistiocytosis
54	Daurismo	Pfizer	Glasdegib	Leukemia (AML)
55	Vitrakvi	Loxo	Larotrectinib	NTRK-positive, non-resistant tumors
56	Firdapse	Catalyst	Amifampridine	Lambert-Eaton myasthenic syndrome
57	Xospata	Astellas	Gilteritinib	Leukemia (AML)
58	Motegrity	Shire	Prucalopride	Chronic idiopathic constipation
59	Asparlas	Servier	Calaspargase pegol-mknl	Leukemia (ALL)
60	Elzonris	Stemline	Tagraxofusp-erzs	Blastic plasmacytoid dendritic cell neoplasm
61	Ultomiris	Alexion	Ravulizumab	Paroxysmal nocturnal hemoglobinuria

Table 1: Drugs approved in 2018 (Rows with grey shading are biologicals).

The first approved drug under the recently generated limited population pathway for antibacterial and antifungal drugs (LPAD) pathway by FDA is Insmed's Arikayce, to treat nontuberculous mycobacterial lung disease. Other firsts included approving the first drug to treat smallpox, SIGA Technologies' Tpoxx; first drug to treat a rare inherited form of rickets known as x-linked hypophosphatemia, Ultragenyx's Crysivita; and the first cannabidiol-based drug, GW Pharmaceuticals' Epidiolex.

The biggest approval of 2018 is Gilead's new HIV therapy Biktarvy, with 5th year predicted US sales of \$4.3 billion [1-3].

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