New Drugs of 2019

In 2019, **48 new prescription drugs were approved** that were considered to be "new molecular entities" (NME) or "new therapeutical biological products." This is the second-highest number of novel drugs approved in one year, but less than in 2018, when 58 novel drugs won U.S. FDA approval. Generics availability continued to grow in 2019, with **98 first-time generic drugs approved**, which is about the same number as last year.

Many of 2019's new drugs treat rare or complicated diseases or conditions. Ten of them are for different kinds of **cancer**, six are for **genetic diseases** (including cystic fibrosis, sickle cell disease, Duchenne, and beta thalassemia) two are for **migraine**, and two treat **skin conditions**. One of them, called **Jeuveau**, is the first neurotoxin specifically approved for a **cosmetic purpose** (improving the appearance of frown lines), and is chemically similar to **Botox**.

Two unusual **antidepressants** were approved in 2019. **Zulresso**, which treats postpartum depression, requires a 3-day stay at a healthcare facility. This is because the medication is administered by I.V. continuously for 60 hours and has risk of loss of consciousness. Another new antidepressant, **Spravato** (not an NME but a new drug formulation based on ketamine), is a nasal spray and must be administered at a certified health care facility because it contains **esketamine**, chemically similar to **ketamine** used as a pre-surgery drug and also in "club drug" known as "Special K." Read more about Spravato: https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified

Here are the novel drugs approved during 2019 and a brief description of the condition they were approved to treat. The list does not include diagnostic drugs such as special dyes used for conducting medical tests.

NEW DRUG	APPROVED TREATMENT
Accrufer	iron deficiency - anemia
Adakveo	sickle cell disease complication
Aklief	acne
Balversa	advanced bladder cancer
Beovu	wet age-related macular degeneration
Brukinsa	mantle cell lymphoma
Caplyta	schizophrenia
Dayvigo	insomnia
Enhertu	metastatic breast cancer
Evenity	osteoporosis if high risk

	of fracture
Fetroja	severe urinary tract infection
Givlaari	hepatic porphyria (blood disorder)
Ibsrela	irritable bowel syndrome with constipation
Inrebic	high-risk primary or secondary myelofibrosis
Jeuveau	cosmetic appearance of facial lines
Mayzent	relapsing multiple sclerosis
Nourianz	Parkinson’s disease experiencing off episodes
Nubeqa	prostate cancer
Oxbryta	sickle cell disease
Padcev	non-responsive bladder cancer
Piqray	breast cancer
Polivy	large B-cell lymphoma
pretomanid	treatment-resistant tuberculosis
Reblozyl	anemia associated with beta thalassemia
Recarbrio	very complicated UTI
Reyvow	acute migraine
Rinvoq	moderate to severe rheumatoid arthritis
Rozlytrek	metastatic non-small cell lung cancer (NSCLC) whose tumors

	are ROS1-positive
Skyrizi	plaque psoriasis
Sunosi	excessive sleepiness
Trikafta	cystic fibrosis
Turalio	tenosynovial giant cell tumor
Ubrelvy	acute migraine
Vyleesi	hyposexual desire disorder in women
Vyndaqel	heart disease caused by ATTR-CM
Vyondys 53	Duchenne muscular dystrophy
Wakix	Excessive daytime sleepiness
Zulresso	postpartum depression

Learn more about the newly approved drugs listed above and view select press releases at the FDA: https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2019

Drug Warnings in 2019

During 2019, there was a surge in the number of safety-related additions or modifications made to drug labels, including **200 "black box" (the most serious) warnings** and more than **700 other safety-related warnings** or contraindications. In 2016, 2017, and 2018 there were 144 black box warnings for all three years combined, according to the U.S. FDA Drug Safety Labeling database. Only a handful of the additions and changes were publicized through press releases.

The **AskaPatient database** will be updated in the next few weeks to include links to all of the safety labeling changes for 2016 -2019.
Here are the most important drug safety communications issued in 2019, with links to FDA press releases:

Valsartan, Losartan, Irbesartan (angiotensin-ii-receptor-blockers)
All year (beginning in 2018): Recalls of this common **blood pressure medication** have been ongoing due to contamination with NDMA.
https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine

Ranitidine (Zantac brand name)

Beginning in September 2019: Recalls of this popular **h-2 blocker for acid reflux** due to contamination with NDMA. Includes brand name and generics.
https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine

Gabapentin (Neurontin, Gralise, Horizant) and Pregabalin (Lyrica)
12/19/2019: These **seizure and pain medications** can cause serious breathing problems.
FDA warns about serious breathing problems with seizure and nerve pain medicines gabapentin (Neurontin, Gralise, Horizant) and pregabalin (Lyrica, Lyrica CR)

Ibrance, Kisqualli, Verzenio
9/13/2019: These **breast cancer drugs** can cause severe lung inflammation.
FDA warns about rare but severe lung inflammation with Ibrance, Kisqali, and Verzenio for breast cancer

Mavret, Zepatier, Vovesi
8/28/2019: These **hepatitis C medicines** can cause serious liver injury.
FDA warns about rare occurrence of serious liver injury with use of hepatitis C medicines Mavyret, Zepatier, and Vosevi in some patients with advanced liver disease

Xeljanz, Xeljanz XR (tocfacitinib)
7/26/2019: These **ulcerative colitis and RA drugs** can increase risk of blood clots and death.
FDA approves Boxed Warning about increased risk of blood clots and death with higher dose of arthritis and ulcerative colitis medicine tofacitinib (Xeljanz, Xeljanz XR)

Lunesta (eszopiclone), Sonata (zaleplon), Ambien, Ambien CR, Edluar, Intermezzo, Zolpimist (zolpidem)
4/30/2019: A new Boxed Warning was added for these **insomnia drugs** because of the risk of serious injuries caused by sleepwalking.
https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-boxed-warning-risk-serious-injuries-caused-sleepwalking-certain-prescription-insomnia

Prescription Opioids (such as Oxycodone, Norco, etc.)
List of Narcotic Pain Relievers
4/9/2019: FDA issues label change warning that sudden discontinuation of **opioid pain medications** can cause harm and prescribers should use gradual, individualized tapering.
FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering

Uloric (febuxostat)
2/21/2019: A new Boxed Warning is added for this **gout drug** that it has an increased risk of death (heart-related and other) compared with another gout medicine, allopurinol.
FDA adds Boxed Warning for increased risk of death with gout medicine Uloric (febuxostat)

AskaPatient Weekly Healthcare Newsletter, January 5, 2020

Please vote in our latest quick poll: How important is it for 2020 presidential candidates to address growing concerns about health care data security?

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