

New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Ayvakit™ (avapritinib)* [†] Blueprint Medicines	Selective KIT and PDGFRA inhibitor	Treatment of adults with unresectable or metastatic gastrointestinal stromal tumor harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations	January 12, 2020
Bynfezia® (octreotide acetate) single-patient-use pen for injection Sun Pharmaceutical	Somatostatin analogue	To reduce blood levels of growth hormone and insulin-like growth factor 1 [somatomedin C] in adult patients with acromegaly who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses; treatment of adult patients with severe diarrhea and flushing episodes associated with metastatic carcinoid tumors; and treatment of adult patients with the profuse watery diarrhea associated with vasoactive intestinal peptide-secreting tumors	TBD
Eylea® (aflibercept) prefilled syringe Regeneron	Vascular endothelial growth factor-A inhibitor/Placental growth factor inhibitor	Treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, and diabetic retinopathy	December 4, 2019
Genosyl® (nitric oxide) Vero Biotech	Vasodilator	To improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (> 34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents	TBD

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Monoferric™ (ferric derisomaltose)* Pharmacosmos	Iron replacement	Treatment of iron deficiency anemia in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron, or who have non-hemodialysis dependent chronic kidney disease	TBD
Numbrino™ (cocaine hydrochloride) Cody Laboratories	Anesthetic	Induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities in adults	February 10, 2020
Palforzia™ (peanut [<i>Arachis hypogaea</i>] allergen powder-dnfp)* Aimmune Therapeutics	Peanut protein capsule	For the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. Palforzia is approved for use in patients with a confirmed diagnosis of peanut allergy.	February 11, 2020
Tazverik™ (tazemetostat)*† Epizyme	Methyltransferase EZH2 inhibitor	Treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection	February 5, 2020
Tepezza™ (teprotumumab-trbw)*† Horizon Therapeutics	Insulin-like growth factor 1 receptor antagonist	Treatment of thyroid eye disease	January 26, 2020
Trijardy™ XR (empagliflozin/linagliptin/ metformin) Boehringer Ingelheim and Eli Lilly	Sodium glucose co-transporter-2 inhibitor/dipeptidyl peptidase 4 inhibitor/biguanide	An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The empagliflozin component is also indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease	TBD
Valtoco® (diazepam)† nasal spray Neurelis	Benzodiazepine	Acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 6 years of age and older	January 14, 2020

*New molecular entity †Orphan Drug TBD: To be determined

New generics

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Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Depen[®] (penicillamine) Mylan	Par [†]	250 mg tablets	Wilson’s disease, cystinuria, and rheumatoid arthritis	January 2, 2020
Silenor[®] (doxepin) Currax	Teva [†]	3 mg, 6 mg tablets	Insomnia characterized by difficulty with sleep maintenance	January 3, 2020
Zohydro[®] ER (hydrocodone) Currax	Alvogent [†]	10 mg, 15 mg, 20 mg, 30 mg, 40 mg, and 50 mg extended-release capsules	Management of severe pain requiring around-the-clock long term opioid treatment	January 24, 2020

†A-rated generic manufacturer

New authorized brand alternatives

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Drug name Manufacturer(s)	Authorized brand alternative manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Humalog[®] Mix[™] 75/25 KwikPen (insulin lispro protamine/insulin lispro) Humalog Junior KwikPen (insulin lispro) Eli Lilly	Eli Lilly	Humalog Mix 75/25: 100 units/mL, 3 mL single- patient-use KwikPen Humalog Junior: 100 units/mL, 3 mL single- patient-use KwikPen	Diabetes mellitus	Mid-April 2020
Silenor[®] (doxepin) Currax	Macoven, Mylan	3 mg, 6 mg tablets	Insomnia characterized by difficulty with sleep maintenance	January 2 - 3, 2020 [‡]

Drug name Manufacturer(s)	Authorized brand alternative manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Symbicort [®] (budesonide/formoterol) AstraZeneca	Prasco	budesonide/formoterol: 160/4.5 mcg and 80/4.5 mcg inhalation aerosol	Asthma and chronic obstructive pulmonary disease including chronic bronchitis and/or emphysema	January 3, 2020
Taclonex [®] (betamethasone dipropionate/calcipotriene) LEO Pharma	Prasco	betamethasone /calcipotriene: 0.064%/0.005% topical suspension	Topical treatment of plaque psoriasis	January 20, 2020
Zohydro [®] ER (hydrocodone) Currax	Macoven	10 mg, 15 mg, 20 mg, 30 mg, 40 mg, and 50 mg extended-release capsules	Management of severe pain requiring around-the-clock long term opioid treatment	January 2, 2020

±Mylan launch date: 1/2/20; Macoven launch date: 1/3/20

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Dificid [®] (fidaxomicin) Merck	Expanded orphan indication, New formulation	Adult and pediatric patients aged 6 months and older for the treatment of <i>Clostridioides difficile</i> -associated diarrhea A new 40 mg/mL (200 mg/5 mL) oral suspension formulation was also approved to support the expanded indication.
Keytruda [®] (pembrolizumab) Merck	Expanded indication	Treatment of patients with Bacillus Calmette-Guerin- unresponsive, high-risk, non-muscle invasive bladder cancer with carcinoma in situ with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy
Ozempic [®] (semaglutide) Novo Nordisk	New indication	To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus (T2DM) and established cardiovascular (CV) disease

<p>Rybelsus[®] (semaglutide) Novo Nordisk</p>	<p>Label update</p>	<p>Data from the cardiovascular safety study was added to the label for Rybelsus. PIONEER 6 is a placebo-controlled, double-blind study in 3,183 patients with inadequately controlled T2DM and atherosclerotic CV disease. Patients were randomized to Rybelsus 14 mg once daily or placebo for a median observation time of 16 months. Rybelsus demonstrated non-inferiority to placebo (hazard ratio = 0.79, 95% confidence interval: 0.57, 1.11).</p>
<p>Sabril[®] (vigabatrin) Lundbeck</p>	<p>Expanded indication</p>	<p>As adjunctive therapy for adults and pediatric patients 2 years of age and older with refractory complex partial seizures who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss</p>

Drug safety news

[Learn more](#)

<p>Drug name Manufacturer(s)</p>	<p>Description</p>
<p>Belvii[®], Belvii XR[®] (lorcaserin)</p>	<p>The FDA announced that results from a clinical trial assessing safety show a possible increased risk of cancer with lorcaserin. The cause of the cancer is uncertain, and the FDA cannot conclude that lorcaserin contributes to the cancer risk.</p>
<p>Clozapine products</p>	<p>The FDA announced that they are strengthening existing warnings in the drug label for all clozapine products regarding clozapine-induced constipation that may progress to serious bowel complications.</p>

Drug recalls/withdrawals/shortages/discontinuations

<p>Drug name Manufacturer(s)</p>	<p>Dosage form(s)</p>	<p>Type</p>	<p>Description</p>
<p>Disulfiram Alvogen and Teva</p>	<p>Alvogen & Teva: 250 mg tablets Teva: 500 mg tablets</p>	<p>Shortage</p>	<p>Generic disulfiram tablets have been unavailable. Per Alvogen, product may be available by the end of March 2020. Teva does not have an estimate as to when product will be available. Alvogen has the product on shortage due to shipping delays. Teva did not provide a reason for the drug shortage.</p> <p>Disulfiram aids in the management of selected chronic alcohol patients who want to remain in a state of enforced sobriety so that supportive and psychotherapeutic treatment may be applied to best advantage.</p>

<p>Lamotrigine Taro Pharmaceuticals</p>	<p>100 mg tablets</p>	<p>Recall</p>	<p>Taro announced a consumer-level recall of lamotrigine tablets because one lot was found to have been cross-contaminated with a small amount of another drug substance, enalapril maleate, used to manufacture another product at the same facility.</p> <p>Lamotrigine is indicated as adjunctive therapy for various types of seizures and for conversion to monotherapy in adults with partial-onset seizures who are receiving other antiepileptic drugs.</p>
<p>Nizatidine Mylan</p>	<p>150 mg, 300 mg capsules</p>	<p>Recall</p>	<p>Mylan announced a consumer-level recall of nizatidine capsules due to detected trace amounts of N-nitrosodimethylamine (NDMA) contained in the active pharmaceutical ingredient, manufactured by Solara Active Pharma Sciences Limited.</p> <p>Nizatidine is indicated for the short-term treatment of active duodenal ulcers and active benign gastric ulcers, as maintenance therapy for duodenal ulcer patients for up to one year, and for up to 12 weeks for the treatment of endoscopically diagnosed esophagitis and associated heartburn due to gastroesophageal reflux disease.</p>
<p>Phospholine Iodide[®] (echothiophate iodide) Pfizer</p>	<p>0.125% (6.25 mg/5 mL) ophthalmic solution</p>	<p>Shortage</p>	<p>Phospholine Iodide has been unavailable due to manufacturing delays. Pfizer estimates that product will be available in the third quarter of 2020.</p> <p>Phospholine Iodide is indicated for the reduction of elevated intraocular pressure and for concomitant esotropias with a significant accommodative component.</p>
<p>Methyldopa Accord and Mylan</p>	<p>250 mg, 500 mg tablets</p>	<p>Shortage</p>	<p>Methyldopa tablets have been unavailable. Accord has temporarily discontinued methyldopa tablets and the company cannot estimate a release date. Mylan's products are not available and their estimated date of availability is sometime in the first quarter of 2020.</p> <p>Methyldopa is indicated for the treatment of hypertension.</p>
<p>Ranitidine Amneal, Appco Pharma, Northwind Pharmaceuticals</p>	<p>Appco: 150 mg, 300 mg capsules Amneal, Northwind: 150 mg, 300 mg tablets</p>	<p>Recall</p>	<p>Amneal Appco Pharma, Northwind Pharmaceuticals announced consumer-level recalls of prescription ranitidine products because of the presence or potential presence of NDMA levels above the acceptable daily intake levels established by the FDA.</p> <p>Prescription ranitidine is used as a short-term treatment for active duodenal ulcers, maintenance therapy for duodenal ulcer patients, treatment of pathological hypersecretory conditions, short-term treatment of active, benign gastric ulcers, maintenance therapy for gastric ulcers, treatment of gastroesophageal reflux disease, and treatment of endoscopically diagnosed erosive esophagitis.</p>

<p>YF-Vax® (yellow fever virus strain 17d-204 live antigen) Sanofi Pasteur</p>	<p>Single- and multi-dose vials</p>	<p>Shortage</p>	<p>YF-Vax has been unavailable due to production delays. Sanofi Pasteur has YF-Vax multi-dose vials and single dose vials on back order and the company cannot estimate a release date.</p> <p>YF-Vax is indicated for active immunization for the prevention of yellow fever.</p>
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Key guideline/literature updates

Topic	Reference
<p>Management of Osteoarthritis of the Hand, Hip and Knee - American College of Rheumatology/Arthritis Foundation</p>	<p><i>Arthritis Care & Research</i>. January 2020</p>
<p>Management of Growth Hormone Deficiency in Adults and Patients Transitioning from Pediatric to Adult Care - American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines</p>	<p><i>American Association of Clinical Endocrinologists</i>. November 2019</p>
<p>Testosterone Treatment in Adult Men with Age-Related Low Testosterone - American College of Physicians</p>	<p><i>Annals of Internal Medicine</i>. January 2020</p>
<p>National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia - Version 1.2020</p>	<p><i>NCCN Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia</i>. January 2020</p>
<p>National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas – Version 1.2020</p>	<p><i>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas</i>. January 2020</p>
<p>National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer – Version 3.2020</p>	<p><i>NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer</i>. January 2020</p>

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer – Version 1.2020	<i><u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer.</u></i> January 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cervical Cancer – Version 1.2020	<i><u>NCCN Clinical Practice Guidelines in Oncology: Cervical Cancer.</u></i> January 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia – Version 3.2020	<i><u>NCCN Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia.</u></i> January 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma – Version 1.2020	<i><u>NCCN Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma.</u></i> January 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Occult Primary – Version 2.2020	<i><u>NCCN Clinical Practice Guidelines in Oncology: Occult Primary.</u></i> January 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Penile Cancer – Version 1.2020	<i><u>NCCN Clinical Practice Guidelines in Oncology: Penile Cancer.</u></i> January 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas – Version 1.2020	<i><u>NCCN Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas.</u></i> January 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: T-Cell Lymphomas – Version 1.2020	<i><u>NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas.</u></i> January 2020

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Vulvar Cancer – Version 1.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Vulvar Cancer.</u> January 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Distress Management – Version 1.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Distress Management.</u> January 2020
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors – Version 2.2020	<u>NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors.</u> January 2020



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