

New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Adhansia XR™ (methylphenidate) Purdue Pharma	Central nervous system stimulant	Treatment of attention deficit hyperactivity disorder in patients 6 years and older	TBD
Cablivi® (caplacizumab-yhdp) [†] Sanofi	Von Willebrand factor-directed antibody	Treatment of adult patients with acquired thrombotic thrombocytopenic purpura, in combination with plasma exchange and immunosuppressive therapy	Late 1Q2019
Egaten™ (triclabendazole) [†] Novartis	Anthelmintic	Treatment of fascioliasis in patients 6 years of age and older	May 2019
Esperoct® (antihemophilic factor [recombinant], glycopegylated-exei) Novo Nordisk	Factor VIII	For use in adults and children with haemophilia A (congenital factor VIII deficiency) for routine prophylaxis to reduce the frequency of bleeding episodes, on-demand treatment and control of bleeding episodes and perioperative management of bleeding	2020+

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Herceptin Hylecta™ (trastuzumab/hyaluronidase- oysk) subcutaneous injection Genentech	HER2/neu receptor antagonist	Adjuvant treatment of adults with HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer: (1) as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel; or (2) as part of a treatment regimen with docetaxel and carboplatin; or (3) as a single agent following multi-modality anthracycline based therapy. In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer. As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease.	TBD
Jeuveau™ (prabotulinumtoxinA-xvfs) [†] Evolus	Botulinum toxins	Temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adults	Spring 2019
Lotemax® SM (loteprednol etabonate) Bausch and Lomb	Corticosteroid	Treatment of post-operative inflammation and pain following ocular surgery	April 2019
Tuxarin™ ER (codeine phosphate and chlorpheniramine maleate) extended release tablets Nexgen Pharma	Opioid/antihistamine	Temporary relief of cough and upper respiratory symptoms associated with allergy or the common cold in patients 18 years of age and older	January 28, 2019
Vancomycin premixed injection Xellia Pharmaceuticals	Glycopeptide antibacterial	In adult and pediatric patients (1 month and older) for the treatment of: septicemia, infective endocarditis, skin and skin structure infections, bone infections, and lower respiratory tract infections	TBD

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

Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Advair Diskus[®] (fluticasone propionate/salmeterol) GlaxoSmithKline	Mylan ^{†§} , Prasco*	fluticasone propionate (100, 250, or 500 mcg) and salmeterol (50 mcg) as a powder formulation for oral inhalation	Asthma and chronic obstructive pulmonary disease	February 8 and 12, 2019 ^Δ
Apadaz[®] (benzhydrocodone/acetaminophen) KVK Tech/KemPath	KVK Tech/KemPath [†]	benzhydrocodone/acetaminophen: 4.08 mg/325 mg, 6.12 mg/325 mg, and 8.16 mg/325 mg tablets	Short-term management of acute pain	February 25, 2019
Ganirelix acetate Organon	Ferring Pharmaceuticals/Sun [†]	250 mcg/0.5mL injection	Inhibition of premature luteinizing hormone surges in women undergoing controlled ovarian hyperstimulation	February 8, 2019
Ranexa[®] (ranolazine) Gilead	Lupin ^{†±}	500 mg and 1000 mg extended-release tablets	Chronic angina	February 28, 2019
Remodulin[®] (treprostinil) United Therapeutics	Sandoz ^{†±}	1 mg/mL, 2.5 mg/mL, 5 mg/mL, and 10 mg/mL injection	Pulmonary arterial hypertension	February 28, 2019
Renagel[®] (sevelamer) Genzyme	Glenmark [†] , Winthrop*	400mg and 800 mg tablets	Control of serum phosphorus in patients with chronic kidney disease on dialysis	February 11 and 14, 2019 [‡]
Suboxone[®] (buprenorphine/naloxone) Indivior	Alvogen [†] , Dr. Reddy's [†] , Sandoz [†] , Mylan [†]	buprenorphine/naloxone 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg sublingual (SL) films	Opioid dependence	February 20 and 22, 2019 [¥]
Zovirax[®] (acyclovir) Bausch Health	Perrigo [†]	5% cream	Recurrent herpes labialis (cold sores)	February 8, 2019

†A-rated generic manufacturer *Authorized generic ±Granted 180 days of marketing exclusivity
 §Branded generic: Wixela Inhub™ Δ2/8: Prasco; 2/12: Mylan
 ¥2/20: Alvogen, Dr. Reddy, and Sandoz launch date; 2/22: Mylan 8 mg and 12 mg SL films
 ‡2/11: Glenmark; 2/14: Winthrop 800 mg tablet

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Keytruda [®] (pembrolizumab) Merck	Expanded indication	Adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection
Lonsurf [®] (trifluridine/tipiracil) Taiho Oncology	New indication	Treatment of adults with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy
Soliqua [®] 100/330 (insulin glargine and lixisenatide) Sanofi	Expanded indication	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
Xultophy [®] 100/3.6 (insulin degludec and liraglutide injection) Novo Nordisk	Expanded indication	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

Drug safety news

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Drug name Manufacturer(s)	Description
Uloric [®] (febuxostat) Takeda Pharmaceuticals	<p>The FDA announced that there is an increased risk of death with Uloric use compared to allopurinol. This conclusion was based on an in-depth review of results from a safety clinical trial that found an increased risk of heart-related death and death from all causes with Uloric.</p> <p>Health care professionals should reserve Uloric for use only in patients who have failed or do not tolerate allopurinol. Patients taking Uloric should be monitored for cardiovascular (CV) signs and symptoms, counseled about the CV risk with Uloric and be advised to seek medical attention immediately if they experience certain symptoms.</p>

<p>Xeljanz™ (tofacitinib) Pfizer</p>	<p>The FDA announced that a safety study found an increased risk of pulmonary embolism (PE) and death when Xeljanz 10 mg twice daily was used in patients with rheumatoid arthritis.</p> <p>Healthcare providers should follow the recommendations in the Xeljanz prescribing information for the specific condition they are treating. Patients should be monitored for the signs and symptoms of PE and advised to seek immediate medical attention if they experience signs and symptoms of PE.</p>
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Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
<p>Gamunex®-C (immune globulin [human]) Grifols</p>	<p>10%, 20 gm/mL injection</p>	<p>Withdrawal</p>	<p>Grifols announced a voluntary, consumer-level withdrawal of one lot of Gamunex-C due to a higher rate of allergic/hypersensitivity type reactions, a small number of which were considered medically significant.</p> <p>Gamunex-C is indicated for the treatment of primary humoral immunodeficiency, idiopathic thrombocytopenic purpura and chronic inflammatory demyelinating polyneuropathy.</p>
<p>Levoleucovorin Mylan</p>	<p>250 mg/25mL injection</p>	<p>Recall</p>	<p>Mylan announced a voluntary recall of two lots of levoleucovorin injection due to the presence of sub-visible particulate matter exceeding the specification.</p> <p>Levoleucovorin is indicated for rescue after high-dose methotrexate therapy in osteosarcoma; to diminish the toxicity and counteract the effects of impaired methotrexate elimination and of inadvertent overdosage of folic acid antagonists; and for use in combination chemotherapy with 5-fluorouracil in the palliative treatment of patients with advanced metastatic colorectal cancer.</p>

Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Losartan Camber Pharmaceuticals	25 mg, 50 mg and 100 mg tablets	Recall	<p>Camber announced a voluntary, consumer-level recall of several lots of losartan tablets due to the detection of trace amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA), a possible process impurity or contaminant in an active pharmaceutical ingredient, manufactured by Hetero Labs.</p> <p>Losartan tablets are used for the treatment of hypertension (HTN); to reduce the risk of stroke in patients with HTN and left ventricular hypertrophy; and for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria in patients with type 2 diabetes and a history of HTN</p>
Losartan/hydrochlorothiazide Macleods	100 mg/25 mg tablets	Recall	<p>Macleods announced a voluntary, consumer-level recall of one lot of losartan/hydrochlorothiazide (HCTZ) tablets due to the detection of trace amounts of an unexpected impurity, identified as N-nitrosodiethylamine (NDEA).</p> <p>Losartan/HCTZ tablets are used for the treatment of HTN and to reduce the risk of stroke in patients with HTN and left ventricular hypertrophy.</p>
Valsartan-containing products Aurobindo Pharma	Amlodipine/valsartan: 10 mg/160 mg tablets Valsartan: 40mg, 80mg 160mg, and 320mg tablets	Recall	<p>Aurobindo Pharma announced a voluntary, consumer-level recall of several lots of valsartan and amlodipine/valsartan tablets due to the detection of trace amounts of an unexpected impurity, identified as N-nitrosodiethylamine.</p> <p>Valsartan is used to control high blood pressure and for the treatment of heart failure. Valsartan in combination with amlodipine is used for the treatment of high blood pressure</p>
Vecuronium Sun Pharma	10 mg, 20 mg injection	Recall	<p>Sun Pharma announced a voluntary, consumer-level recall of several lots of vecuronium injection due to foreign matter identified as glass detected in one vial to date.</p> <p>Vecuronium bromide is indicated as an adjunct to general anesthesia, to facilitate endotracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation.</p>

Key guideline/literature updates

Topic	Reference
Advisory Committee on Immunization Practices – Vaccine Recommendations and Guidelines	<i>Annals of Internal Medicine</i> . February 2019
American College of Allergy, Asthma, and Immunology – Asthma Controller Step-Down Yardstick	<i>Annals of Allergy, Asthma & Immunology</i> . March 2019
Hellenic Association for the Study of the Liver - Autoimmune hepatitis	<i>Annals of Gastroenterology</i> . January 2019
Infectious Diseases Society of America – 2018 Update on Influenza	<i>Clinical Infectious Diseases</i> . December 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Antiemesis – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Antiemesis</i> . February 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer – Version 4.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer</i> . February 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer Associated Venous Thromboembolic Disease – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Cancer Associated Venous Thromboembolic Disease</i> . February 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma – Version 3.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma</i> . February 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kidney Cancer – Version 3.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer</i> . February 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Malignant Pleural Mesothelioma – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Malignant Pleural Mesothelioma</i> . February 2019

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Palliative Care – Version 2.2019	<i><u>NCCN Clinical Practice Guidelines in Oncology: Palliative Care.</u></i> February 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma – Version 2.2019	<i><u>NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma.</u></i> February 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thymomas and Thymic Carcinomas – Version 1.2019	<i><u>NCCN Clinical Practice Guidelines in Oncology: Thymomas and Thymic Carcinomas.</u></i> February 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Uterine Neoplasms – Version 3.2019	<i><u>NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms.</u></i> February 2019



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