

New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Bijuva™ (estradiol/progesterone) TherapeuticsMD	Estrogen/progesterone	Treatment of moderate to severe vasomotor symptoms due to menopause in women with a uterus	Second quarter of 2019
Hyrimoz™ (adalimumab-adaz) ^{§*} Sandoz	Tumor necrosis factor inhibitor	Rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, ulcerative colitis, plaque psoriasis	TBD
Khapzory™ (levoleucovorin) Spectrum	Folate analog	Rescue after high-dose methotrexate therapy in patients with osteosarcoma, diminishing the toxicity associated with overdosage of folic acid antagonists or impaired methotrexate elimination, and for the treatment of patients with metastatic colorectal cancer in combination with fluorouracil.	January 2019
Nuzyra™ (omadacycline) [*] Paratek	Tetracycline	Treatment of adult patients with the following infections caused by susceptible microorganisms: community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections	First quarter of 2019

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Panzyga® (immune globulin intravenous, human - ifas) Octapharma	Immune globulin	Treatment of primary humoral immunodeficiency in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, WiskottAldrich syndrome, and severe combined immunodeficiencies. Treatment of adult patients with chronic immune thrombocytopenia to raise platelet counts to control or prevent bleeding.	October 17, 2018
Qmiiz ODT™ (meloxicam) TerSera Therapeutics	Nonsteroidal anti-inflammatory drug	Relief of the signs and symptoms of osteoarthritis in adults; rheumatoid arthritis in adults; and pauciarticular and polyarticular course juvenile rheumatoid arthritis in pediatric patients who weigh greater than or equal to 60 kg	TBD
Revcovi™ (elapegademase-lvlr) [†] Leadiant Biosciences	Enzyme replacement therapy	Treatment of adenosine deaminase severe combined immune deficiency in pediatric and adult patients	TBD
Seysara™ (sarecycline) [*] Almirall, Paratek	Tetracycline	Treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older	January 2019
Symjepi™ (epinephrine) 0.15 mg injection Adamis	Catecholamine	Emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (eg, order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (eg, triatoma, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (eg, radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis	TBD
Talzenna® (talazoparib) [*] Pfizer	Poly (ADP-ribose) polymerase (PARP) inhibitor	Treatment of adults with deleterious or suspected deleterious germline breast cancer susceptibility gene-mutated human epidermal growth factor receptor 2-negative locally advanced or metastatic breast cancer	October 18, 2018

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Tegsedi™ (inotersen) [†] Akcea Therapeutics, Ionis	Transthyretin-directed antisense oligonucleotide	Treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults	October 23, 2018
Xofluza™ (baloxavir marboxil) [*] Genentech	Polymerase acidic endonuclease inhibitor	Treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours	October 25, 2018
Xyosted™ (testosterone enanthate) Antares Pharma	Androgen	Testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone	November 1, 2018
Yutiq™ (fluocinolone acetonide intravitreal implant) EyePoint Pharmaceuticals	Corticosteroid	Treatment of chronic non-infectious uveitis affecting the posterior segment of the eye	First quarter of 2019

*New molecular entity †Orphan Drug §Biosimilar 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
AndroGel® (testosterone) AbbVie	Perrigo [†] , Zydus [*]	1.62% metered dose pump and unit-dose packets	Deficiency or absence of endogenous testosterone	October 15, 2018

Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Onfi [®] (clobazam) Lundbeck	Amneal [†] , Breckenridge [†] , Hetero [†] , Hikma/West- Ward [†] , Mylan [†] , Piramal [†] , Upsher- Smith [†] , Taro [†] , Zydus [†] and Bionpharma [†]	10 mg and 20 mg tablets, 2.5 mg/mL oral suspension	Seizures associated with Lennox-Gastaut syndrome	October 23, 2018 [±]
Zytiga [®] (abiraterone) Janssen	Mylan [†] , Teva [†] , Apotex [†] , Hikma [†]	250 mg tablet	Prostate cancer	Fourth quarter of 2018

[†]A-rated generic manufacturer *Authorized generic [±]Launch date for all manufacturers

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Afluria [®] Quadrivalent (influenza vaccine) Seqirus	Expanded indication	For active immunization against influenza disease for persons 6 months of age and older
Dupixent [®] (dupilumab) Regeneron, Sanofi	New indication, new warnings	Add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma New warnings were added to the Dupixent drug label regarding eosinophilic conditions, acute asthma symptoms or deteriorating disease, and reduction of corticosteroid dosage
Gardasil [®] 9 (human papillomavirus 9-valent vaccine [HPV], recombinant) Merck	Expanded indication	Use in males and females aged 9 through 45 years, for the prevention of certain cancers and diseases caused by nine HPV types
Hemlibra [®] (emicizumab-kxwh) Genentech	Expanded indication	Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients ages newborn and older with hemophilia A with or without factor VIII inhibitors

Drug name Manufacturer(s)	Type	Description
Humira [®] (adalimumab) AbbVie	Expanded indication	Treatment of moderate to severe hidradenitis suppurativa in patients ≥ 12 years of age
Invokana [®] (canagliflozin), Invokamet [®] (canagliflozin/metformin), Invokamet XR (canagliflozin/metformin extended release) Janssen	New indication	To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease
Keytruda [®] (pembrolizumab) Merck	Expanded indication	In combination with carboplatin and either paclitaxel or Abraxane [®] (nab-paclitaxel), as first-line treatment of patients with metastatic squamous non-small cell lung cancer
Liletta [®] (levonorgestrel-releasing intrauterine system) Allergan, Medicines360	Expanded indication	Prevention of pregnancy for up to 5 years
Stiolto [®] Respimat [®] (olodaterol/tiotropium) Boehringer Ingelheim	Expanded indication	Long-term, once-daily maintenance treatment of patients with chronic obstructive pulmonary disease, including chronic bronchitis and/or emphysema
Trintellix [®] (vortioxetine) Takeda	Indication update	Treatment of major depressive disorder in adults
Xarelto [®] (rivaroxaban) Janssen	New indication	In combination with aspirin, to reduce the risk of major cardiovascular events in patients with chronic coronary artery disease or peripheral artery disease
Xyrem [®] (sodium oxybate) Jazz	Expanded indication	Treatment of cataplexy or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy

Drug safety news

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Drug name Manufacturer(s)	Description
Rituxan® (rituximab) Biogen, Genentech	Information regarding retreatment in patients with granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA) was removed from the <i>Warnings and Precautions</i> section of the Rituxan drug label. The dosing section was updated with information on induction treatment and follow up treatment for GPA and MPA.
Taxotere® (docetaxel) Sanofi-Aventis	The <i>Warnings and Precautions</i> section of the Taxotere drug label was updated with information regarding the risk of enterocolitis and neutropenic colitis.

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Aminophylline injection Hospira	250 mg/10 mL and 500 mg/10 mL single dose vials	Shortage	The drug shortage of aminophylline injection is ongoing. Hospira estimates that product will be available by the first quarter of 2019. Intravenous theophylline (aminophylline) is indicated as an adjunct to inhaled beta-2 selective agonists and systemically administered corticosteroids for the treatment of acute exacerbations of the symptoms and reversible airflow obstruction associated with asthma and other chronic lung diseases (eg, emphysema and chronic bronchitis).
Erwinaze® (asparaginase <i>Erwinia chrysanthemi</i>) Jazz	10,000 IU lyophilized powder supplied in a 3 mL vial	Shortage	The drug shortage of Erwinaze is ongoing. Jazz estimates that new orders will be filled by the end of November. Erwinaze is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia who have developed hypersensitivity to <i>E. coli</i> -derived asparaginase.

Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Intravenous solutions ICU Medical	0.9% sodium chloride injection 50 mL, 100 mL, 150 mL, and 250 mL flexible containers; 5% dextrose injection 25 mL and 250 mL flexible containers	Recall	ICU Medical announced a user-level recall of some lots of sodium chloride and dextrose intravenous solutions due to the potential for flexible container leaks.
Irbesartan ScieGen	75 mg, 150 mg and 300 mg tablets	Recall	ScieGen Pharmaceuticals (labeled as Westminster Pharmaceuticals and Golden State Medical Supplies) announced a consumer-level recall of several lots of irbesartan tablets due to the detection of trace amounts of an unexpected impurity, identified as nitrosodiethylamine (NDEA), found in an active pharmaceutical ingredient manufactured by Aurobindo Pharmaceuticals.
Mustargen[®] (mechlorethamine) Recordati Rare Diseases	10 mg injection	Discontinuation	<p>The FDA announced the discontinuation of Mustargen injection. Recordati has decided to discontinue manufacture, distribution and sale of Mustargen due to extremely low demand. Sales will be allowed through December 31, 2018.</p> <p>Mustargen, administered intravenously, is indicated for the palliative treatment of Hodgkin's disease, lymphosarcoma, chronic myelocytic or chronic lymphocytic leukemia, polycythemia vera, mycosis fungoides, and bronchogenic carcinoma.</p>
ReoPro[®] (abciximab) Janssen Biotech	2 mg/mL, 5 mL vial	Shortage	<p>The drug shortage of ReoPro is ongoing. Reopro has been unavailable due to a long-term shortage of an ingredient from a third party manufacturer. Janssen Biotech does not have an estimated time frame as to when the shortage will resolve.</p> <p>Reopro is indicated as an adjunct to percutaneous coronary intervention for the prevention of cardiac ischemic complications: in patients undergoing percutaneous coronary intervention and in patients with unstable angina not responding to conventional medical therapy when percutaneous coronary intervention is planned within 24 hours.</p>

Key guideline/literature updates

Topic	Reference
American Diabetes Association and the European Association for the Study of Diabetes - Management of Hyperglycemia in Type 2 Diabetes	<i>Diabetes Care</i> . October 2018
American Gastroenterological Association Institute - Medical Management of Opioid-Induced Constipation	<i>Gastroenterology</i> . October 2018
American Society of Clinical Oncology and Infectious Diseases Society of America - Antimicrobial Prophylaxis for Adult Patients With Cancer-Related Immunosuppression	<i>Journal of Clinical Oncology</i> . September 2018
American Thoracic Society, European Respiratory Society, Japanese Respiratory Society, and Latin American Thoracic Society - Idiopathic Pulmonary Fibrosis	<i>American Journal of Respiratory and Critical Care Medicine</i> . September 2018
Global Initiative for Chronic Obstructive Lung Disease - Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease	<i>GOLD Report</i> . October 2018
Society of Critical Care Medicine - Prevention and Management of Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption in Adult Patients in the ICU	<i>Critical Care Medicine</i> . September 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: AIDS-Related Kaposi Sarcoma – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: AIDS-Related Kaposi Sarcoma</i> . October 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas – Version 5.2018	<i>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas</i> . October 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer – Version 3.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer</i> . October 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cervical Cancer – Version 2.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Cervical Cancer</i> . October 2018

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma – Version 2.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma.</i> October 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer – Version 4.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer.</i> October 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers – Version 4.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers.</i> October 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes – Version 2.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes.</i> October 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms – Version 2.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms.</i> October 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</i> October 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer.</i> October 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Squamous Cell Skin Cancer – Version 2.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Squamous Cell Skin Cancer.</i> October 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Systemic Light Chain Amyloidosis – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Systemic Light Chain Amyloidosis.</i> October 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Testicular Cancer – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Testicular Cancer.</i> October 2018

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Uterine Neoplasms – Version 1.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms.</u> October 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis – Version 3.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis.</u> October 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prevention and Treatment of Cancer-Related Infections – Version 1.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Prevention and Treatment of Cancer-Related Infections.</u> October 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adolescent and Young Adult (AYA) Oncology – Version 1.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Adolescent and Young Adult (AYA) Oncology.</u> October 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer in People Living with HIV – Version 1.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Cancer in People Living with HIV.</u> October 2018



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