

New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
AirDuo[®] Digihaler[™] (fluticasone propionate/salmeterol) Teva	Corticosteroid/ long-acting beta agonist (LABA)	Treatment of asthma in patients aged 12 years and older. AirDuo Digihaler should be used for patients not adequately controlled on a long term asthma control medication such as an inhaled corticosteroid or whose disease warrants initiation of treatment with both an inhaled corticosteroid and LABA	TBD
Accrufer[®] (ferric maltol) Shield Therapeutics	Iron replacement	Treatment of iron deficiency in adults	TBD
Angiomax[®] RTU (bivalrudin) MAIA Pharmaceuticals	Direct thrombin inhibitor	Anticoagulant in patients undergoing percutaneous coronary intervention, including patients with heparin-induced thrombocytopenia and heparin-induced thrombocytopenia and thrombosis syndrome	TBD
Baqsimi[™] (glucagon) nasal powder Eli Lilly	Glucagon analog	Treatment of severe hypoglycemia in patients with diabetes ages 4 years and above	July 28, 2019
Cuvitru (immune globulin subcutaneous [human], 20% solution) 10 mg/50 mL subcutaneous injection Baxalta	Immunoglobulin	Replacement therapy for primary humoral immunodeficiency in adult and pediatric patients two years of age and older	July 2, 2019

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Drizalma Sprinkle ™ (duloxetine) delayed release capsules Sun Pharma	Serotonin and norepinephrine reuptake inhibitor	Treatment of major depressive disorder in adults; generalized anxiety disorder in adults and pediatric patients ages 7 years to 17 years old; diabetic peripheral neuropathic pain in adults; and chronic musculoskeletal pain in adults	TBD
Hadlima ™ (adalimumab-bwwd) ^{*§} Samsung Bioepis	Tumor necrosis factor inhibitor	Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, ulcerative colitis, and plaque psoriasis	TBD
Kanjinti ™ (trastuzumab-anns) ^{*§} Allergan and Amgen	HER-2/neu receptor antagonist	Adjuvant breast cancer, metastatic breast cancer, and metastatic gastric or gastroesophageal junction adenocarcinoma	July 22, 2019
Katerzia ™ (amlodipine) oral suspension Silvergate Pharmaceuticals	Calcium channel blocker	Treatment of hypertension in adults and children 6 years and older, to lower blood pressure; symptomatic treatment of chronic stable angina; treatment of confirmed or suspected vasospastic angina; to reduce the risk of hospitalization for angina and to reduce the risk of a coronary revascularization procedure in patients with recently documented coronary artery disease by angiography and without heart failure or an ejection fraction < 40%	July 16, 2019
Mvasi ™ (bevacizumab-awwb) [§] Allergan and Amgen	Vascular endothelial growth factor inhibitor	Metastatic colorectal cancer; unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer; recurrent glioblastoma; metastatic renal cell carcinoma; and persistent, recurrent, or metastatic carcinoma of the cervix	July 22, 2019
Nubeqa ® (darolutamide)* Bayer	Androgen receptor inhibitor	Treatment of patients with non-metastatic castration resistant prostate cancer	July 30, 2019
Ortikos ® (budesonide) extended-release capsules Sun Pharma	Corticosteroid	Treatment of mild to moderate active Crohn's disease involving the ileum and/or the ascending colon in patients 8 years of age and older; maintenance of clinical remission of mild to moderate Crohn's disease involving the ileum and/or the ascending colon for up to 3 months in adults	TBD

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Recarbrio™ (imipenem/cilastatin/relebactam)* Merck	Carbapenem/dehydropeptidase-1 inhibitor/beta-lactamase inhibitor	In patients 18 years of age and older who have limited or no alternative treatment options, for the treatment of complicated urinary tract infections, including pyelonephritis, caused by certain susceptible gram-negative microorganisms; or for the treatment of complicated intra-abdominal infections caused by certain gram-negative microorganisms	TBD
Ruxience™ (rituximab-pvvr) [§] Pfizer	Monoclonal antibody	Treatment of relapsed or refractory, low grade or follicular, CD20-positive B-cell non-Hodgkin's lymphoma (NHL) as a single agent; previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy; and non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone chemotherapy; previously untreated and previously treated CD20-positive chronic lymphocytic leukemia in combination with fludarabine and cyclophosphamide	TBD
Xembify® (immune globulin subcutaneous, human - klhw) Grifols	Immune globulin	Treatment of primary humoral immunodeficiency in patients 2 years of age and older	4Q2019
Xpovio™ (selinexor) [†] Karyopharm	Selective inhibitor of nuclear export	In combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody	July 9, 2019

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

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New generics

Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Firazyr [®] (icatibant) Shire	Teva [†] , Takeda [*]	30 mg/3 mL injection	Hereditary angioedema	July 16, 2019 [¥]
Hemabate [®] (carboprost tromethamine) Pfizer	Dr. Reddy's ^{†±}	250 mcg/mL injection	For aborting pregnancy and postpartum hemorrhage	July 3, 2019
Lyrica [®] (pregabalin) Pfizer	Rising Pharmaceuticals [†] , Alkem [†] , Amneal [†] , Dr. Reddy's [†] , Invagen [†] , Novadoz/MSN Labs [†] , Sciegen [†] , Teva [†] , Greenstone	25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg capsules	Neuropathic pain associated with diabetic peripheral neuropathy; postherpetic neuralgia; fibromyalgia; neuropathic pain associated with spinal cord injury; and adjunctive therapy for partial-onset seizures	July 19, 2019 ^Δ
	Ascend Laboratories [†] , Greenstone	20 mg/mL oral solution		July 23, 2019 [#]
Rozerem [®] (ramelteon) Takeda	Teva [†] , Dr. Reddy's [†] , Zydus [†]	8 mg tablets	Insomnia characterized by difficulty with sleep onset	July 23, 2019
Uloric [®] (febuxostat) Takeda	Alembic [†] , Mylan [†] , Sun Pharma [†] , Macleods [†]	40 mg and 80 mg tablets	Chronic management of hyperuricemia in patients with gout	July 1, 2019 [§]

[†]A-rated generic manufacturer ^{*}Authorized brand alternatives (also known as authorized generic) [±]Granted 180 days of marketing exclusivity

[¥]Teva launch date; Takeda launched 8/1/19

^ΔRising and MSN/Novadoz launch date; Amneal, Teva and Greenstone launched on 7/22/19; other manufacturers TBD

[#]Ascend launch date; Greenstone launched 7/29/19

[§]Alembic, Mylan and Sun Pharma launch date; Macleods TBD

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Enstilar[®] (calcipotriene/betamethasone dipropionate) Leo Pharma	Expanded indication	Topical treatment of plaque psoriasis in patients 12 years of age and older
Keytruda[®] (pembrolizumab) Merck	New indication	Treatment of patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1, with disease progression after one or more prior lines of systemic therapy
Otezla[®] (apremilast) Celgene	New orphan indication	Treatment of adults with oral ulcers associated with Behçet's disease
Taclonex[®] (calcipotriene/betamethasone dipropionate) Leo Pharma	Expanded indication	Topical treatment of plaque psoriasis of the scalp and body in patients 12 years and older

Drug safety news

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Drug name Manufacturer(s)	Description
Venclexta[®] (venetoclax) Abbvie	The FDA approved an update to the <i>Warnings and Precautions</i> section of the Venclexta drug label, regarding increased mortality in patients with multiple myeloma when Venclexta is added to Velcade [®] (bortezomib) and dexamethasone.
Xeljanz[®], Xeljanz XR (tofacitinib) Pfizer	The FDA announced that a new <i>Boxed Warning</i> will be added to the tofacitinib (Xeljanz, Xeljanz XR) drug label regarding an increased risk of pulmonary embolism and death with the 10 mg twice daily dose in patients with ulcerative colitis (UC). The approved use of tofacitinib for UC will be limited to certain patients who are not treated effectively or who experience severe side effects with certain other medicines.

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Clobazam oral suspension Bionpharma	2.5 mg/mL, 120 mL bottle	Recall	<p>The FDA announced a recall of one lot of Bionpharma's clobazam oral suspension due to microbial contamination.</p> <p>Clobazam oral suspension is indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in patients 2 years of age or older.</p>
Drospirenone/ethinyl estradiol tablets Jubilant Cadista	drospirenone/ethinyl estradiol 3 mg/0.02 mg tablets	Recall	<p>Jubilant Cadista announced a recall of one lot of drospirenone/ethinyl estradiol tablets due to out-of-specification dissolution results at the 3-month stability time point, which may lead to decreased product efficacy.</p> <p>Drospirenone/ethinyl estradiol tablets are indicated for use by women to: prevent pregnancy; treat symptoms of premenstrual dysphoric disorder; and to treat moderate acne.</p>
Kogenate[®] FS antihemophilic factor (recombinant) Bayer	2000 IU vials	Recall	<p>Bayer recalled two lots of Kogenate FS antihemophilic factor because some of the vials contained Jivi[®] antihemophilic factor (recombinant) PEGylated-aucl 3000 IU.</p> <p>Kogenate FS is used to replace clotting factor that is missing in people with hemophilia A. Kogenate FS is approved to treat or control bleeding in adults and children with hemophilia A.</p>
Sodium chloride injection Baxter	0.9% injection, 100 mL VIAFLEX plastic container, multi pack	Recall	<p>Baxter recalled two lots of sodium chloride injection due to the potential presence of leaks.</p> <p>Sodium chloride injection is indicated as a source of water and electrolytes and for use as a priming solution in hemodialysis procedures.</p>

Key guideline/literature updates

Topic	Reference
American Academy of Dermatology and National Psoriasis Foundation - Care for the Management and Treatment of Psoriasis with Biologics	<i>Journal of the American Academy of Dermatology</i> . April 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer – Version 4.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer</i> . July 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer– Version 2.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer</i> . July 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma – Version 2.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma</i> . July 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma – Version 3.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma</i> . July 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma – Version 1.2020	<i>NCCN Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma</i> . July 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal – Version 2.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal</i> . July 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adolescent and Young Adult (AYA) Oncology – Version 1.2020	<i>NCCN Clinical Practice Guidelines in Oncology: Adolescent and Young Adult (AYA) Oncology</i> . July 2019

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer in People Living with HIV – Version 2.2019	<u>NCCN Clinical Practice Guidelines in Oncology: Cancer in People Living with HIV.</u> July 2019



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