

New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Aemcolo™ (rifamycin) Cosmo	DNA-dependent RNA polymerase inhibitor	Treatment of travelers' diarrhea caused by non-invasive strains of <i>Escherichia coli</i> in adults	First quarter of 2019
Bryhali™ (halobetasol propionate) lotion Bausch Health, Ortho Dermatologics	Corticosteroid	Topical treatment of plaque psoriasis in adults	November 13, 2018
Daurismo™ (glasdegib) [†] Pfizer	Hedgehog inhibitor	Treatment of newly-diagnosed acute myeloid leukemia in adult patients who are ≥ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy	November 28, 2018
Dsuvia™ (sufentanil) [*] AcelRx	Opioid agonist	Use in adults in a certified medically supervised healthcare setting, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate	First quarter of 2019
Egrifta® (tesamorelin) single dose vial for injection Theratechnologies	Growth hormone-releasing hormone receptor agonist	Reduction of excess abdominal fat in HIV-infected patients with lipodystrophy	TBD
Firdapse® (amifampridine) ^{††} Catalyst	Broad spectrum potassium channel blocker	Treatment of Lambert-Eaton myasthenic syndrome in adults	First quarter of 2019

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Gamifant [®] (emapalumab-lzsg) [†] Novimmune, Sovi	Interferon gamma blocking antibody	Treatment of adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy	First quarter of 2019
Lorbrena [®] (lorlatinib) [†] Pfizer	Tyrosine kinase inhibitor	Treatment of patients with anaplastic lymphoma kinase-positive metastatic non-small cell lung cancer whose disease has progressed on: Xalkori [®] (crizotinib) and at least one other ALK inhibitor for metastatic disease; or Alecensa [®] (alectinib) or Zykadia [®] (ceritinib) as the first ALK inhibitor therapy for metastatic disease.	November 6, 2018
Primatene [®] Mist (epinephrine) [±] Amphastar	Bronchodilator	Temporary relief of mild symptoms of intermittent asthma (ie, wheezing, tightness of chest, and shortness of breath) in adults and children 12 years of age and older This version of Primatene Mist contains hydrofluoroalkane propellants, which are permitted under current U.S. law.	Early 2019
Sympazan [™] (clobazam) Aquestive Therapeutics	Benzodiazepine	Adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome in patients 2 years of age or older	November 5, 2018
Temixys [™] (lamivudine/tenofovir disoproxil fumarate) Celltrion	Nucleoside reverse transcriptase inhibitor	In combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 infection in adults and pediatric patients weighing at least 35 kg	TBD
Truxima [®] (rituximab-abbs) ^{*§} Teva, Celltrion	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.	TBD

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Udenyca™ (pegfilgrastim-cbqv) ^{*§} Coherus BioSciences	Colony-stimulating factor	To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia	November 30, 2018
Vitrekvi® (larotrectinib) ^{*†} Loxo Oncology	Kinase inhibitor	Treatment of adult and pediatric patients with solid tumors that: (1) have a neurotrophic receptor tyrosine kinase gene fusion without a known acquired resistance mutation, (2) are metastatic or where surgical resection is likely to result in severe morbidity, and (3) have no satisfactory alternative treatments or that have progressed following treatment	November 26, 2018
Xospata™ (gilteritinib) ^{*†} Astellas	Tyrosine kinase inhibitor	Treatment of adult patients who have relapsed or refractory acute myeloid leukemia with a FMS-like tyrosine kinase 3 mutation as detected by an FDA-approved test	November 28, 2018
Yupelri™ (revefenacin) [*] Theravance Biopharma	Long-acting muscarinic antagonist	Maintenance treatment of patients with chronic obstructive pulmonary disease	November 15, 2018

*New molecular entity †Orphan Drug §Biosimilar ±OTC approval 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
Finacea® (azelaic acid) Bayer	Sandoz [*]	15% gel	Rosacea	November 13, 2018
Levitra® (vardenafil) GlaxoSmithKline	Lannett [†] , Zydus Cadila [†]	2.5 mg, 5 mg, 10 mg and 20 mg tablets	Erectile dysfunction	November 1, 2018

Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Minivelle [®] (estradiol) Noven	Noven Grove [†] , Mylan [†]	0.025 mg, 0.0375 mg, 0.05 mg, 0.075 mg, and 0.1 mg transdermal systems	Vasomotor symptoms due to menopause and for the prevention of postmenopausal osteoporosis	November 2, 2018 [±]
Rapaflo [®] (silodosin) Allergan	Lupin [†] , Sandoz [†]	4 mg and 8 mg capsules	Benign prostatic hyperplasia	November 27, 2018
Staxyn [®] (vardenafil) Bayer	Alembic [†]	10 mg orally disintegrating tablet	Erectile dysfunction	November 21, 2018
Vusion [®] (miconazole/white petrolatum/zinc oxide) Mylan	Mylan [*]	miconazole 2.5 mg/white petrolatum 813.5 mg/150 mg zinc oxide mg ointment	Diaper dermatitis	November 6, 2018
Zytiga [®] (abiraterone acetate) Janssen	Apotex [†] , Hikma [†] , Mylan [†] , Patriot [*] , and Teva [†]	250 mg tablets	Metastatic prostate cancer	November 23, 2018

†A-rated generic manufacturer *Authorized generic ±Launch date for Noven Grove; Mylan launch is TBD

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Adcetris [®] (brentuximab vedotin) Seattle Genetics	New indication	Treatment of systemic anaplastic large cell lymphoma or other CD30-expressing peripheral T-cell lymphomas
Astagraf XL [®] (tacrolimus) Astellas	Expanded indication	Prophylaxis of organ rejection in kidney transplant patients in adult and pediatric patients

Drug name Manufacturer(s)	Type	Description
Empliciti [®] (elotuzumab) Bristol-Myers Squibb	New indication	In combination with Pomalyst [®] (pomalidomide) and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least two prior therapies including Revlimid [®] (lenalidomide) and a proteasome inhibitor
Keytruda [®] (pembrolizumab) Merck	New indication	Treatment of patients with hepatocellular carcinoma who have been previously treated with Nexavar [®] (sorafenib)
Oralair [®] (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens allergen extract) Stallergenes Greer	Expanded indication	Treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis for certain pollen-specific IgE antibodies in patients 5 to 65 years of age
Promacta [®] (eltrombopag) Novartis	Expanded indication	First-line treatment of adult and pediatric patients 2 years and older with severe aplastic anemia
Venclexta [®] (venetoclax) AbbVie, Roche	New indication	Treatment of newly-diagnosed acute myeloid leukemia in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy

Drug safety news

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Drug name Manufacturer(s)	Description
EpiPen [®] (epinephrine) Mylan	The labels attached to some EpiPen 0.3 mg and EpiPen Jr 0.15 mg auto-injectors, and the authorized generic versions, may block access to the auto-injector and prevent the ability to easily access the product.
Gilenya [®] (fingolimod) Novartis	A warning about the potential risk of severe increase in disability when Gilenya therapy is stopped will be added to the Gilenya drug label and patient Medication Guide.

Idhifa [®] (enasidenib) Celgene	The FDA announced that signs and symptoms of a life-threatening side effect called differentiation syndrome are not being recognized in patients receiving Idhifa. Idhifa carries a boxed warning for differentiation syndrome and information is in the patient medication guide. However, the FDA has become aware of cases of differentiation syndrome not being recognized and patients not receiving the necessary treatment.
Lemtrada [®] (alemtuzumab) Genzyme	The FDA announced that a new warning about the rare but serious cases of stroke and tears in the lining of arteries in the head and neck occurring in patients taking Lemtrada will be added to the Lemtrada drug label and patient Medication Guide. The risk of stroke will also be added to Lemtrada's <i>Boxed Warning</i> .
Regranex [®] (becaplermin) Smith & Nephew	The FDA approved the removal of the <i>Boxed Warning</i> and the warning in the <i>Warnings and Precautions</i> section of the Regranex drug label regarding increased rate of mortality secondary to malignancy.
Seroquel [®] / Seroquel XR [®] (quetiapine) AstraZeneca	The FDA approved an update to the <i>Warnings and Precautions</i> section of the Seroquel and Seroquel XR drug labels regarding the risk of anticholinergic effects.

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
CoaguChek [®] XS PT Test Strips Roche	Test strips	Recall	Roche announced a consumer-level recall of some lots of CoaguChek XS PT test strips because some patients have been experiencing inaccurately high International Normalized Ratio test results due to a re-calibration of the test strips due to a different international standard.
Losartan/hydrochlorothiazide Sandoz	100 mg/25 mg tablets	Recall	Sandoz announced a voluntary, consumer-level recall of one lot of losartan/hydrochlorothiazide tablets due to the detection of trace amounts of an unexpected impurity, identified as n-nitrosodiethylamine contained in the active pharmaceutical ingredient losartan, manufactured by Zhejiang Huahai Pharmaceutical.

Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Methyldopa Accord, Mylan	250 mg and 500 mg tablets	Shortage	<p>The drug shortage of methyldopa tablets is ongoing. Accord's methyldopa tablets are temporarily discontinued with no estimated release date. Mylan's methyldopa 250 mg and 500 mg tablets are estimated to be available by February 2019 and March 2019, respectively.</p> <p>Methyldopa is indicated for the treatment of hypertension.</p>
Sodium phosphate injection Fresenius Kabi, Hospira	phosphorus 15 mmol/mL, 5 mL, sodium 20 mEq/5mL injection; phosphorus 45 mmol/15 mL, sodium 60 mEq/15 mL injection; and phosphorous 45 mmol/15 mL, sodium 4 mEq/mL injection	Shortage	<p>The drug shortage of sodium phosphate injection is ongoing. Fresenius Kabi estimates that product will be available sometime in December 2018. Hospira estimates that product will be available by September 2019.</p>
Valsartan-containing products Mylan	valsartan: 40 mg, 80 mg, 160 mg, 320 mg tablets amlodipine/valsartan: 5 mg/160 mg, 10 mg/160 mg, and 10 mg/320 mg tablets valsartan/HCTZ: 320 mg/25 mg tablets	Recall	<p>Mylan announced a voluntary, consumer-level recall of several lots of valsartan, amlodipine/valsartan, and valsartan/HCTZ tablets due to the detection of trace amounts of an unexpected impurity, identified as n-nitrosodiethylamine, found in an active pharmaceutical ingredient manufactured by Mylan Laboratories Limited.</p>
Valsartan-containing products Teva	amlodipine/valsartan: 5 mg/160 mg, 10 mg/160 mg, and 10 mg/320 mg tablets amlodipine/valsartan/HCTZ 5 mg/160 mg/12.5 mg, 10 mg/160 mg/12.5 mg, 10 mg/160 mg/25 mg and 10 mg/320 mg/25 mg tablets	Recall	<p>Teva announced a voluntary, consumer-level recall of all lots of amlodipine/valsartan combination tablets and amlodipine/valsartan/HCTZ combination tablets due to an impurity, NDEA, detected above specification limits in an active pharmaceutical ingredient manufactured by Mylan India.</p>

Key guideline/literature updates

Topic	Reference
American College of Cardiology/American Heart Association - Management of Blood Cholesterol	<i>Circulation</i> . November 2018
American College of Cardiology Expert Consensus Decision Pathway on Novel Therapies for Cardiovascular Risk Reduction in Patients With Type 2 Diabetes and Atherosclerotic Cardiovascular Disease	<i>Journal of the American College of Cardiology</i> . November 2018
American Society of Hematology – Venous Thromboembolism	<i>American Society of Hematology</i> . November 2018
Opioid-Prescribing Guidelines for Common Surgical Procedures	<i>Journal of the American College of Surgeons</i> . October 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia – Version 3.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia</i> . November 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: AIDS-Related Kaposi Sarcoma – Version 2.2019	<i>NCCN Clinical Practice Guidelines in Oncology: AIDS-Related Kaposi Sarcoma</i> . November 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas</i> . November 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Central Nervous System Cancers – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Central Nervous System Cancers</i> . November 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cutaneous Melanoma – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Cutaneous Melanoma</i> . November 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers – Version 5.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers</i> . November 2018

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities</i> . November 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma – Version 2.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma</i> . November 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer – Version 2.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer</i> . November 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma</i> . November 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas</i> . November 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: T-Cell Lymphomas – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas</i> . November 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thyroid Carcinoma – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma</i> . November 2018



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