

New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Aristada Initio™ (aripiprazole lauroxil) extended release injectable suspension Alkermes	Antipsychotic	In combination with oral aripiprazole for the initiation of Aristada when used for the treatment of schizophrenia in adults	July 3, 2018
Azedra® (iobenguane I 131) [†] Progenics	Radiopharmaceutical	Treatment of patients ≥ 12 years of age with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy	TBD
Glyrx-PF™ (glycopyrrolate) Exela	Anticholinergic	In anesthesia for reduction of salivary, tracheobronchial, and pharyngeal secretions, reduction of volume and acidity of gastric secretions, and blockade of cardiac inhibitory reflexes during induction of anesthesia and intubation; intraoperatively to counteract surgically or drug-induced or vagal reflex-associated arrhythmias; for protection against peripheral muscarinic effects of cholinergic agents such as neostigmine and pyridostigmine given to reverse the neuromuscular blockade due to non-depolarizing agents As adjunctive therapy for the treatment of peptic ulcer in adults when rapid anticholinergic effect is desired or when oral medication is not tolerated	TBD

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Infugem™ (gemcitabine) Sun Pharma	Nucleoside metabolic inhibitor	<p>In combination with carboplatin, for the treatment of advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy;</p> <p>In combination with paclitaxel, for first-line treatment of metastatic breast cancer after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated;</p> <p>In combination with cisplatin for the first-line treatment of inoperable, locally advanced (stage IIIA or IIIB), or metastatic (stage IV) non-small cell lung cancer;</p> <p>The first-line treatment of locally advanced (nonresectable stage II or stage III) or metastatic (stage IV) adenocarcinoma of the pancreas, in patients previously treated with fluorouracil</p>	TBD
Kaspargo™ (metoprolol succinate) extended-release capsule Sun Pharmaceutical Industries	Beta1-selective adrenergic receptor blocking agent	Treatment of hypertension, to lower blood pressure; Long-term treatment of angina pectoris, to reduce angina attacks and to improve exercise tolerance; Reduce the risk of cardiovascular mortality and heart-failure hospitalization in patients with heart failure	July 3, 2018
Krintafel™ (tafenoquine) [†] GlaxoSmithKline	Antimalarial	Radical cure (prevention of relapse) of <i>Plasmodium vivax</i> malaria in patients ≥ 16 years and older who are receiving appropriate antimalarial therapy for acute <i>P. vivax</i> infection	2 nd half of 2018
Mulpleta® (lusutrombopag) [*] Shionigi	Thrombopoietin receptor agonist	Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure	Early September 2018

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Nivestym™ (filgrastim-aafi) ^{†§} Pfizer	Granulocyte-colony stimulating factor	<p>To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever</p> <p>For reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia</p> <p>To reduce the duration of neutropenia and neutropenia-related clinical sequelae, eg, febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation</p> <p>For the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis</p> <p>To reduce the incidence and duration of sequelae of neutropenia (eg, fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia</p>	TBD
Omegaven® (fish oil triglycerides) Fresenius Kabi	Lipid source	As a source of calories and fatty acids in pediatric patients with parenteral nutrition-associated cholestasis	TBD
Orilissa™ (elagolix) [*] AbbVie	Gonadotropin-releasing hormone receptor antagonist	Management of moderate to severe pain associated with endometriosis	July 25, 2018
Perseris™ (risperidone) extended-release injectable suspension Indivior, Durect	Atypical antipsychotic	Treatment of schizophrenia in adults	TBD
Remodulin® (treprostinil) extended-release injection [†] United Therapeutics	Prostacyclin analog	Treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to diminish symptoms associated with exercise, and to diminish the rate of clinical deterioration in patients with PAH who require transition from Flolan® (epoprostenol) for use with the implantable system for Remodulin (ISR)	TBD

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Symtuza™ (darunavir/cobicistat/ emtricitabine/tenofovir alafenamide) Janssen	Protease inhibitor/NRTI/boosting agent/NRTI	A complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who have no prior antiretroviral (ARV) treatment history or who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable ARV regimen for at least 6 months and have no known substitutions associated with resistance to darunavir or tenofovir	July 19, 2018
Tibsovo® (ivosidenib) [†] Agiros	Isocitrate dehydrogenase-1 inhibitor (IDH1)	Treatment of adult patients with relapsed or refractory acute myeloid leukemia with a susceptible IDH1 mutation as detected by an FDA-approved test	July 23, 2018
TPOXX® (tecovirimat) ^{*†} SIGA Technologies	Orthopoxvirus VP37 envelope wrapping protein	Treatment of human smallpox disease caused by variola virus in adults and pediatric patients weighing at least 13 kg	TBD

*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
Clindagel® (clindamycin phosphate) Valeant	Oceanside [*]	1% topical gel	Treatment of acne vulgaris	July 5, 2018
Cosopt® PF (dorzolamide/timolol) Akorn	Aurobindo [†]	2% / 0.5% preservative-free ophthalmic solution	Reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	July 26, 2018
Luzu™ (luliconazole) Valeant	Oceanside [*]	1% cream	Treatment of interdigital tinea pedis, tinea cruris, and tinea corporis	July 5, 2018

Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Topicort [®] (desoximetasone) Taro	Lupin [†]	0.25% topical spray	Treatment of plaque psoriasis	July 23, 2018
Torisel [®] (temsirolimus) Pfizer	Accord [†]	25 mg/mL injection	Treatment of advanced renal cell carcinoma.	TBD
Uceris [®] (budesonide) Salix	Teva [†]	9 mg extended-release tablets	Induction of remission in patients with ulcerative colitis	July 8, 2018
Veltin [®] (clindamycin phosphate/tretinoin) Aqua	Prasco Laboratories [*]	1.2% / 0.025% topical gel	Topical treatment of acne vulgaris	July 6, 2018
Welchol [®] (colesevelam hydrochloride) Daiichi Sankyo	Glenmark [†] , Sun [*]	1.875 grams/packet and 3.75 grams/packet for oral suspension	Reduce elevated low-density lipoprotein cholesterol levels and improve glycemic control	July 18, 2018

†A-rated generic manufacturer *Authorized generic TBD: To be determined

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Atripla [®] (efavirenz/emtricitabine/tenofovir disoproxil fumarate) Gilead	Expanded indication, new contraindication	Treatment of HIV-1 infection in patients weighing ≥ 40 kg. A new update has been added to the <i>Contraindications</i> section indicating that Atripla is contraindicated for coadministration with Zepatier [®] (elbasvir/grazoprevir).

Drug name Manufacturer(s)	Type	Description
Granix[®] (tbo-filgrastim) Teva	Expanded indication, new warnings	Treatment of patients \geq 1 month old for reduction in the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Updates were made the <i>Warnings and Precautions</i> section of the Granix drug label regarding leukocytosis, simultaneous use with chemotherapy and radiation therapy not recommended, nuclear imaging, and aortitis.
Intelence[®] (etravirine) Janssen	Expanded indication	Treatment of HIV-1 infection in ARV treatment-experienced patients \geq 2 years of age, who have evidence of viral replication and HIV-1 strains resistant to a non-nucleoside reverse transcriptase inhibitor and other ARV agents.
Kisqali[®] (ribociclib) Novartis	Expanded indications, new warning	In combination with an aromatase inhibitor for the treatment of pre/perimenopausal or postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, as initial endocrine-based therapy. In combination with Faslodex [®] (fulvestrant) for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy. A new warning has been added to the Kisqali drug label regarding QT prolongation with concomitant use of tamoxifen.
Lotemax[®] (loteprednol etabonate) Valeant	Expanded indication	Treatment of post-operative inflammation and pain following ocular surgery in adults and pediatric patients.
Opdivo[®] (nivolumab) Bristol-Myers Squibb	Expanded indication	In combination with Yervoy (ipilimumab) for the treatment of microsatellite instability high or mismatch repair deficient metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.
Signifor[®] LAR (pasireotide) Novartis	New indication	Treatment of Cushing's disease.
Yervoy[®] (ipilimumab) Bristol-Myers Squibb	Expanded indication	In combination with Opdivo (nivolumab) for the treatment of microsatellite instability high or mismatch repair deficient metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

Drug name Manufacturer(s)	Type	Description
Xeomin [®] (incobotulinumtoxinA) Merz North America	New indication	Treatment of chronic sialorrhea.
Xtandi [®] (enzalutamide) Astellas Pharma, Pfizer	Expanded indication, new warnings	Treatment of patients with castration-resistant prostate cancer. New updates have been added to the <i>Warnings and Precautions</i> section of the drug label regarding hypersensitivity reactions, ischemic heart disease, falls and fractures, and embryo-fetal toxicity.
Zomacton [®] (somatropin) Ferring	New indications	Treatment of pediatric patients with short stature associated with Turner syndrome; idiopathic short stature; short stature or growth failure in short stature homeobox-containing gene deficiency; and short stature born small for gestational age.

Drug safety news

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Drug name Manufacturer(s)	Description
Fluoroquinolone Antibiotics	The <i>Warnings and Precautions</i> section of the fluoroquinolone antibiotics drug labels were updated with information on risks of low blood sugar and mental health adverse reactions.
Lamictal [®] (lamotrigine)	The <i>Warnings and Precautions</i> section of the Lamictal drug label was updated with information regarding the risk of hemophagocytic lymphohistiocytosis.

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Valsartan and Valsartan-Hydrochlorothiazide (HCTZ) Products Various manufacturers and repackagers	Valsartan: 40 mg, 80 mg, 160 mg, and 320 mg tablets Valsartan-HCTZ: 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg, 320 mg/12.5 mg, and 320 mg/25 mg tablets	Recall	The FDA initiated a series of announcements regarding the patient-level recall of certain batches of valsartan and valsartan-HCTZ tablets because of unacceptable levels of chemical known as N-nitrosodimethylamine.
Vaniqa ™ (eflornithine) Allergan	13.9% cream	Shortage	The drug shortage of Allergan's Vaniqa is ongoing due to a shortage of the active ingredient. The estimated date of availability is September 30, 2018. Vaniqa is indicated for the reduction of unwanted facial hair in women.

Key guideline/literature updates

Topic	Reference
American College of Gastroenterology - Crohn's Disease Management	<i>American Journal of Gastroenterology</i> . March 2018
American Academy of Neurology – Disease-Modifying Therapies for Adults with Multiple Sclerosis	<i>Neurology</i> . April 2018

Topic	Reference
American Society of Clinical Oncology – Systemic Therapies for Patients With Advanced Human Epidermal Growth Factor Receptor 2-Positive Breast Cancer	<i>Journal of Clinical Oncology</i> . June 2018
American Society of Clinical Oncology – Recommendations on Disease Management for Patients With Advanced Human Epidermal Growth Factor Receptor 2-Positive Breast Cancer and Brain Metastases	<i>Journal of Clinical Oncology</i> . June 2018
International Antiviral Society – USA Panel: Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults	<i>Journal of the American Medical Association</i> . July 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer – Version 5.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer</i> . July 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast and Ovarian – Version 2.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast and Ovarian</i> . July 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal – Version 1.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal</i> . July 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Melanoma – Version 3.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Melanoma</i> . July 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma Carcinoma</i> . July 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes – Version 1.2019	<i>NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes</i> . July 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma</i> . July 2018

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Survivorship – Version 1.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Survivorship</i> . July 2018



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