

New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Aimovig™ (erenumab-aooe)* Amgen, Novartis	Calcitonin gene-related peptide antagonist	Preventive treatment of migraine in adults	May 20, 2018
Andexxa® (coagulation factor Xa [recombinant], inactivated-zhzo)* Portola	Recombinant factor Xa inhibitor antidote	For patients treated with Xarelto® (rivaroxaban) and Eliquis® (apixaban), when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding	May 14, 2018
Bendamustine ready-to-dilute solution Eagle	Alkylating agent	Treatment of patients with chronic lymphocytic leukemia; Treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen	TBD
Consensi® (amlodipine/celecoxib) Kitov Pharma	Nonsteroidal anti-inflammatory drug/Calcium channel blocker	For patients for whom treatment with amlodipine for hypertension and celecoxib for osteoarthritis are appropriate	TBD
Doptelet® (avatrombopag)* Dova	Thrombopoietin receptor agonist	Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure	May 30, 2018

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Imvexxy [™] (estradiol vaginal inserts) TherapeuticsMD	Estrogens	Treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause	July 2018
Lokelma [™] (sodium zirconium cyclosilicate) AstraZeneca	Potassium binder	Treatment of hyperkalemia in adults	TBD
Lucemyra [™] (lofexidine) [*] US WorldMeds	Alpha-2 adrenergic agonist	Mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults	May 27, 2018
Olumiant [®] (baricitinib) [*] Eli Lilly, Incyte	Janus associated kinase 1/2 inhibitor	Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor antagonist therapies	End of the second quarter of 2018
Palynziq [™] (pegvaliase-pqpz) [*] BioMarin	Enzyme replacement	To reduce blood phenylalanine (Phe) concentrations in adult patients with phenylketonuria who have uncontrolled blood Phe concentrations > 600 micromol/L on existing management	May 31, 2018
Plenvu [®] (polyethylene glycol 3350/sodium ascorbate/sodium sulfate/ascorbic acid/sodium chloride/potassium chloride) Norgine, Salix	Osmotic laxative	Cleansing of the colon in preparation for colonoscopy in adults	Second half of 2018
Prograf [®] (tacrolimus) 0.2 mg and 1 mg granules for oral suspension Astellas	Immunosuppressant	Prophylaxis of organ rejection, in patients receiving allogeneic liver, kidney, or heart transplants, in combination with other immunosuppressants	Early 2019

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Retacrit™ (epoetin alfa-epbx) [§] Hospira, Pfizer	Erythropoiesis-stimulating agent	Treatment of anemia due to chronic kidney disease, chemotherapy, or use of zidovudine in patients with human immunodeficiency virus-infection; Reduce the need for allogeneic red blood cell transfusions among patients with perioperative hemoglobin > 10 to ≤ 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery	TBD
Yonsa® (abiraterone) Sun Pharma	Tyrosine kinase inhibitor	Treatment of patients with metastatic castration-resistant prostate cancer in combination with methylprednisolone	May 29, 2018

*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
Cialis® (tadalafil) Eli Lilly	Teva [†]	2.5 mg, 5 mg, 10 mg, 20 mg tablets	Erectile dysfunction, benign prostatic hyperplasia	September 2018
Quelicin® (succinylcholine chloride) Hospira	Zydus [†]	20 mg/mL, 50 mg/mL, 100 mg/mL solution for injection	Endotracheal intubation and skeletal muscle relaxation for surgical procedures or mechanical ventilation	TBD
Mephyton® (phytonadione) Valeant	Amneal [†] , Oceanside [†]	5 mg tablets	Coagulation disorders	May 15, 2018
Plan B One-Step® (levonorgestrel) Teva	Combe ^{††}	1.5 mg tablet	Emergency contraceptive	TBD

Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Welchol [®] (colesevelam) Daiichi Sankyo	Amneal [†] , Glenmark [†] , Sun Pharma [*]	625 mg tablets	Hyperlipidemia, type 2 diabetes mellitus	May 17, 2018

[†]A-rated generic manufacturer [‡]Over-the-Counter; Branded generic marketed as Preventeza ^{*}Authorized generic TBD: To be determined

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Arnuity [®] Ellipta [®] (fluticasone furoate) GlaxoSmithKline	Expanded indication	Maintenance treatment of asthma as prophylactic therapy in patients ≥ 5 years of age To support the expanded indication, Arnuity Ellipta will be available as a new 50 mcg/actuation formulation.
Briviact [®] (brivaracetam) tablets and oral solution UCB	Expanded indication	Treatment of partial-onset seizures in patients ≥ 4 years of age
Cimzia [®] (certolizumab pegol) UCB	New indication	Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
Darzalex [®] (daratumumab) Janssen	Expanded indication	Treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant in combination with Velcade [®] (bortezomib), melphalan, and prednisone
Gilenya [®] (fingolimod) Novartis	New indication	Treatment of relapsing forms of multiple sclerosis in patients ≥ 10 years of age
Kymriah [™] (tisagenlecleucel) Novartis	New indication	Treatment of adults with relapsed or refractory large B-cell lymphoma after 2 or more lines of systemic therapy

Drug name Manufacturer(s)	Type	Description
Lyrica [®] (pregabalin) Pfizer	Expanded indication	Adjunctive therapy for the treatment of partial onset seizures in patients ≥ 4 years of age
Prolia [®] (denosumab) Amgen	New indication	Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture
Tafinlar [®] (dabrafenib), Mekinist [®] (trametinib) Novartis	New indications	Tafinlar in combination with Mekinist for the adjuvant treatment of melanoma with BRAF V600E or V600K mutations, and involvement of lymph node(s), following complete resection; Treatment of locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation and with no satisfactory locoregional treatment options [†]
Truvada [®] (emtricitabine/tenofovir disoproxil fumarate) Gilead	Expanded indication	In combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually active human immunodeficiency virus type 1 in at-risk adolescents weighing ≥ 35 kg
Xeljanz [®] (tofacitinib) Pfizer	New indication	Treatment of adults with moderately to severely active ulcerative colitis

†Orphan Indication

Drug safety news

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Drug name Manufacturer(s)	Description
Dolutegravir-containing products	The FDA announced that serious cases of neural tube birth defects have been reported in babies born to women treated with dolutegravir [ie, Juluca [®] (dolutegravir/rilpivirine), Tivicay [®] (dolutegravir), and Triumeq [®] (abacavir/dolutegravir/lamivudine)]. Preliminary results from an ongoing observational study in Botswana found that women who received dolutegravir at the time of becoming pregnant or early in the first trimester appear to be at higher risk for these defects.

<p>Epivir® (lamivudine), Epzicom® (abacavir/lamivudine) ViiV Healthcare Company</p>	<p>Information regarding lactic acidosis and severe hepatomegaly was removed from the Boxed Warning section of the drug labels.</p>
<p>Keytruda® (pembrolizumab), Tecentriq® (atezolizumab) Merck, Genentech</p>	<p>Decreased survival is associated with the use of Keytruda or Tecentriq as monotherapy to treat patients with metastatic urothelial cancer who have not received prior therapy and who have low expression of the protein programmed death ligand 1.</p>
<p>Oral benzocaine products</p>	<p>Over-the-counter benzocaine products should not be used to treat infants and children < 2 years of age. The FDA is also warning that these products should only be used in adults and children ≥ 2 years of age if they contain certain warnings on the drug label. Benzocaine products carry serious risks and provide little to no benefits for treating oral pain, including sore gums in infants due to teething. Benzocaine can cause methemoglobinemia, a condition that can be life-threatening and result in death.</p>

Drug recalls/withdrawals/shortages/discontinuations

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<p>Drug name Manufacturer(s)</p>	<p>Dosage form(s)</p>	<p>Type</p>	<p>Description</p>
<p>Ampicillin/sulbactam and piperacillin/tazobactam injection products AuroMedics</p>	<p>Ampicillin/sulbactam for injection 3 grams per single dose vial Piperacillin/tazobactam for injection, 3.375 grams per single-dose vial</p>	<p>Recall</p>	<p>Ampicillin/sulbactam is being recalled due to customer complaints of the presence of red particulate matter in the product that is believed to be red rubber particles from the manufacturing process of the active ingredients. Piperacillin/tazobactam is being recalled due to particulate matter, visible only after reconstitution, which was confirmed to be glass within the vial.</p>
<p>Accu-Chek® Aviva Plus Test Strips Roche</p>	<p>Test strips</p>	<p>Recall</p>	<p>Several lots of Accu-Chek Aviva Plus Test Strips were recalled because some had cracked reagent. The cracked reagent may lead to an increased potential for strip errors prior to applying a blood sample, strips not detected once inserted, or in a very limited number of cases an inaccurate result may occur (which may not be detectable).</p>
<p>Fluticasone propionate nasal spray Apotex</p>	<p>50 mcg per spray, 120 metered sprays</p>	<p>Recall</p>	<p>One lot of fluticasone propionate nasal spray is being recalled due to small glass particles, which could block the actuator and impact the functionality of the pump.</p>

Drug name Manufacturer(s)	Dosage form(s)	Type	Description
<p>Lanoxin[®] (digoxin) Concordia</p>	<p>187.5 mcg tablet</p>	<p>Discontinuation</p>	<p>Lanoxin 187.5 mcg tablets are being discontinued due to business reasons. This product discontinuation is not related to product quality, safety, or efficacy issues. The anticipated final date of availability is June 30, 2018.</p> <p>Lanoxin is indicated for heart failure and atrial fibrillation.</p>
<p>Levitra[®] (vardenafil) Bayer</p>	<p>2.5 mg tablet</p>	<p>Discontinuation</p>	<p>Levitra 2.5 mg tablets are being discontinued. This product discontinuation is not related to product quality, safety, or efficacy issues. Bayer will continue to market the 5 mg, 10 mg and 20 mg tablet strengths.</p> <p>Levitra is indicated for the treatment of erectile dysfunction.</p>
<p>Piperacillin/tazobactam injection Apotex</p>	<p>3.375 grams per single-dose vial and 4.5 grams per single dose vial</p>	<p>Recall</p>	<p>Several lots of piperacillin/tazobactam injection were recalled because of elevated levels of impurities that may result in decreased potency.</p>
<p>Taytulla[®] (norethindrone acetate/ethinyl estradiol and ferrous fumarate) Allergan</p>	<p>1 mg/20 mcg, 6 x 28 sample pack</p>	<p>Recall</p>	<p>One lot of Taytulla capsules were recalled because of a report stating that a physician's sample pack had four placebo capsules that were placed out of order.</p>
<p>Technivie[™] (ombitasvir/paritaprevir/ritonavir), Viekira XR[™] (dasabuvir/ombitasvir/paritaprevir/ritonavir) AbbVie</p>	<p>Viekira XR: dasabuvir 200 mg/ombitasvir 8.33 mg/paritaprevir 50 mg/ritonavir 33.33 mg extended-release tablet Technivie: ombitasvir 12.5 mg/paritaprevir 75 mg / ritonavir 50 mg tablet</p>	<p>Discontinuation</p>	<p>Technivie and Viekira XR are being voluntarily discontinued due to changes in treatment practices in the current chronic hepatitis C virus (HCV) market in the U.S. and are not related to quality, safety or efficacy issues.</p> <p>Until January 1, 2019, supply of Technivie and Viekira XR will be available for all patients who begin therapy prior to July 1, 2018 to ensure that they are able to complete their course of prescribed therapy.</p> <p>Viekira Pak[™] (ombitasvir/paritaprevir/ritonavir with dasabuvir) will continue to be available.</p> <p>Viekira XR and Technivie are indicated for the treatment of HCV infection.</p>

Key guideline/literature updates

Topic	Reference
Management of Bleeding in Patients Taking Oral Anticoagulants – American College of Cardiology	<i>Journal of the American Medical Association</i> . May 2018
Castration-Resistant Prostate Cancer – American Urological Association	<i>American Urological Association</i> . May 2018
Management of Crohn’s Disease in Adults – American College of Gastroenterology	<i>The American Journal of Gastroenterology</i> . May 2018
Diagnosis and Treatment of Neurocysticercosis - Infectious Diseases Society of America and the American Society of Tropical Medicine and Hygiene	<i>The American Society of Tropical Medicine and Hygiene</i> . May 2018
Disease-modifying Therapies for Adults with Multiple Sclerosis - American Academy of Neurology	<i>Neurology</i> . April 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas – Version 4.2018	<i>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas</i> . May 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer – Version 4.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer</i> . May 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis</i> . May 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers</i> . May 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastric Cancer – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer</i> . May 2018

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors.</i> May 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: T-Cell Lymphomas – Version 4.2018	<i>NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas.</i> May 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thyroid Carcinoma – Version 1.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma Carcinoma.</i> May 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Uterine Neoplasms – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms.</i> May 2018



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