

March 2018

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New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Cimduo [™] (lamivudine/tenofovir disoproxil fumarate) Mylan	Nucleo(t)side reverse transcriptase inhibitor	Treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 35 kg in combination with other antiretroviral agents	Second quarter of 2018
Ilumya [™] (tildrakizumab-asmn) [*] Sun Pharma	Interleukin-23 inhibitor	Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy	TBD
Symfi [™] (efavirenz/lamivudine/tenofovir disoproxil fumarate) Mylan	Non-nucleoside reverse transcriptase inhibitor/nucleo(t)side reverse transcriptase inhibitor	Treatment of HIV-1 infection in adult and pediatric patients weighing ≥ 40 kg	Second quarter of 2018
Trogarzo [™] (ibalizumab-uiyk) ^{*†} Theratechnologies, TaiMed Biologics	Viral entry inhibitor	Treatment of HIV-1 infection in combination with other antiretroviral(s) in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen	March 20, 2018

*New molecular entity †Orphan Drug 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
Aloxi [®] (palonosetron) Eisai	Teva [†] , Dr. Reddy [†] , Cipla [†] , Sandoz [†] , Exela [†] , Fresenius Kabi [‡]	0.25 mg/5 mL injection	Prevention of chemotherapy-induced and postoperative nausea and vomiting	March 23, 2016 [¥]
Norvir [®] (ritonavir) AbbVie	West-Ward [†]	100 mg tablet	Human immunodeficiency virus-1 infection	March 12, 2018
Prevacid [®] SoluTab [™] (lansoprazole) Takeda	Teva [†]	15 mg and 30 mg delayed-release orally disintegrating tablets	Management of acid-related disorders	March 8, 2018
Sensipar [®] (cinacalcet) Amgen	Aurobindo [†] , Cipla [†]	30 mg, 60 mg, 90 mg tablets	Secondary hyperparathyroidism, parathyroid carcinoma, and primary hyperparathyroidism	TBD
Safyral [™] (drospirenone/ethinyl estradiol/levomefolate calcium) Bayer	Lupin [§]	3 mg/0.03 mg/0.451 mg tablets	Prevention of pregnancy	March 13, 2018

†A-rated generic manufacturer *Authorized generic TBD: To be determined
 ¥Launch date for Teva; Dr. Reddy and Cipla: March 26, 2018; all other manufacturers are TBD ‡Approved as a New Drug Approval §Branded generic marketed as Tydemyl

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Adcetris [®] (brentuximab vedotin) Seattle Genetics	New indication	Treatment of adults with previously untreated stage III/IV classical Hodgkin lymphoma, in combination with chemotherapy
Blincyto [™] (blinatumomab) Amgen	Expanded orphan indication	Treatment of B-cell precursor acute lymphoblastic leukemia in first or second complete remission with minimal residual disease ≥ 0.1% in adults and children

Drug name Manufacturer(s)	Type	Description
Hizentra [®] (immune globulin subcutaneous [human], 20%) CSL Behring	New orphan indication	Treatment of adults with chronic inflammatory demyelinating polyneuropathy as maintenance therapy to prevent relapse of neuromuscular disability and impairment
Latuda [®] (lurasidone) Sunovion	Expanded indication	Monotherapy treatment of patients 10 to 17 years of age with major depressive episode associated with bipolar I disorder (bipolar depression)
Leukine [®] (sargramostim) Partner Therapeutics	New indication, safety updates	<p>Increase survival in patients acutely exposed to myelosuppressive doses of radiation</p> <p>The <i>Contraindications</i> section has been updated to state that Leukine should not be administered to patients with a history of serious allergic reactions, including anaphylaxis, to human granulocyte-macrophage colony stimulating factor such as sargramostim, yeast-derived products, or any component of the product.</p> <p>The <i>Warnings and Precautions</i> section was updated to include infusion related reactions and risk of severe myelosuppression when administered within 24 hours of chemotherapy or radiotherapy.</p>
Otiprio [®] (ciprofloxacin otic suspension) Otonomy	New indication	Treatment of acute otitis externa in patients ≥ 6 months of age due to <i>Pseudomonas aeruginosa</i> and <i>Staphylococcus aureus</i>
Tasigna [®] (nilotinib) Novartis	New and expanded indications; safety update	<p>Treatment of pediatric patients ≥ 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia in chronic phase and pediatric patients ≥ 1 year of age with Philadelphia chromosome positive chronic myeloid leukemia with resistance or intolerance to prior tyrosine-kinase inhibitor therapy</p> <p>The <i>Warnings and Precautions</i> section was updated with information on effects on growth and development in pediatric patients. Information regarding food effects and drug interactions were removed from the <i>Warnings and Precautions</i> section.</p>

Drug safety news

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Drug name Manufacturer(s)	Description
Agrylin[®] (anagrelide hydrochloride) Shire	Information regarding pulmonary hypertension was added to the <i>Warnings and Precautions</i> section of the Agrylin drug label.
Asmanex[®] HFA and Asmanex[®] Twisthaler[®] (mometasone furoate) Merck	Information regarding excessive use of Dulera [®] (mometasone furoate/formoterol fumarate) and use with other long-acting beta ₂ -agonists, cardiovascular and central nervous system effects, coexisting conditions, and hypokalema/hyperglycemia were removed from the <i>Warnings and Precautions</i> section of the Asmanex HFA and Asmanex Twisthaler drug labels.
Emend[®] (fosaprepitant) injection Merck	Information regarding infusion site reactions was added to the <i>Warnings and Precautions</i> section of the Emend drug label. Infusion site reactions have been reported with Emend for injection.
Tecentriq[®] (atezolizumab) Genentech	Information regarding myocarditis was added to the <i>Warnings and Precautions</i> section of the Tecentriq drug label.
Torisel[®] (temsirolimus) Pfizer	Information regarding proteinuria and nephrotic syndrome was added to and laboratory monitoring was removed from the <i>Warnings and Precautions</i> section of the Torisel drug label.

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Alka-Seltzer Plus[®] products Bayer	Packages of Alka-Seltzer Plus sold after February 9, 2018 with a logo with an orange or green background	Recall	Bayer announced a voluntary, consumer-level recall of Bayer's Alka-Seltzer Plus packages sold after February 9, 2018, because the ingredients on the front sticker may not match the actual product in the carton.

Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Methylprednisolone injection Sagent	40 mg, 125 mg and 1 g injection	Recall	<p>Sagent announced a voluntary, user-level recall of ten lots of methylprednisolone injection due to high out of specification impurity results detected during routine quality testing of stability samples for two lots. This impurity has not yet been identified.</p> <p>Methylprednisolone sodium succinate is an anti-inflammatory glucocorticoid indicated for a number of conditions.</p>
Twynsta [®] (telmisartan/amlodipine) Boehringer Ingelheim	80 mg/10 mg tablets	Discontinuation	<p>The FDA announced the discontinuation of Twynsta 80 mg/10 mg tablets due to a business decision. All other strengths of Twynsta tablets are available. The discontinuation is not due to product quality, safety or efficacy concerns.</p> <p>Twynsta is indicated for the treatment of hypertension.</p>
Zinbryta [®] (daclizumab) Biogen, AbbVie	150 mg/mL prefilled autoinjector and 150 mg/mL prefilled syringe	Withdrawal	<p>Biogen and AbbVie have voluntarily withdrawn marketing authorizations for Zinbryta due to the nature and complexity of adverse events being reported with Zinbryta use. The manufacturers have determined that the evolving benefit/risk profile of Zinbryta will not be possible going forward given the limited number of patients being treated.</p> <p>Healthcare providers should evaluate individual patient circumstances and consider the pharmacodynamics effects of Zinbryta to determine an appropriate plan for discontinuation. Certain liver function tests (transaminase levels and total bilirubin) should be measured monthly for 6 months after the last dose of Zinbryta. Zinbryta will be available until April 30, 2018.</p> <p>Zinbryta is indicated for the treatment of adult patients with relapsing forms of multiple sclerosis.</p>

Key guideline/literature updates

Topic	Reference
Evaluation and Treatment of Hirsutism in Premenopausal Women - Endocrine Society	<i>The Journal of Clinical Endocrinology and Metabolism</i> . March 2018
Hemoglobin A _{1c} Targets for Glycemic Control With Pharmacologic Therapy for Nonpregnant Adults With Type 2 Diabetes Mellitus – American College of Physicians	<i>Annals of Internal Medicine</i> . March 2018
<p>Praluent[®] (alirocumab) – ODYSSEY Outcomes Study Results</p> <p>ODYSSEY demonstrated that Praluent significantly reduced the risk of major adverse cardiovascular events in patients who had suffered a recent acute coronary syndrome event.</p>	<i>American College of Cardiology 67th Scientific Session</i> . March 2018
Testosterone Therapy in Men With Hypogonadism - Endocrine Society Clinical	<i>The Journal of Clinical Endocrinology and Metabolism</i> . March 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia – Version 1.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia</i> . March 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer – Version 3.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer</i> . March 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bone Cancer – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Bone Cancer</i> . March 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer – Version 1.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer</i> . March 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Central Nervous System Cancers – Version 1.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Central Nervous System Cancers</i> . March 2018

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma – Version 5.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma.</i> March 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer.</i> March 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers – Version 1.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers.</i> March 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastric Cancer – Version 1.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer.</i> March 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors – Version 1.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors.</i> March 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer.</i> March 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Penile Cancer – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Penile Cancer.</i> March 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer.</i> March 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer – Version 1.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer.</i> March 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma.</i> March 2018

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Uveal Melanoma – Version 1.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Uveal Melanoma.</u> March 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma – Version 1.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma Melanoma.</u> March 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening – Version 1.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening.</u> March 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection – Version 1.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection.</u> March 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Antiemesis – Version 1.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Antiemesis.</u> March 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer-Associated Venous Thromboembolic Disease – Version 1.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Cancer-Associated Venous Thromboembolic Disease.</u> March 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloid Growth Factors – Version 1.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Myeloid Growth Factors.</u> March 2018



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