

RxHighlights

September 2022

New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Aponvie™ (aprepitant) 32 mg/4.4 mL injectable emulsion Heron Therapeutics	Substance P/neurokinin-1 receptor antagonist	Prevention of postoperative nausea and vomiting in adults	TBD
Daxxify™ (daxibotulinumtoxinA-1anm)* Revance Therapeutics	Botulinum toxin	Temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.	TBD
Lytgobi® (futibatinib) [†] Taiho Oncology	Fibroblast growth factor receptor inhibitor	Treatment of adult patients with previously treated unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 gene fusions or other rearrangements	TBD
Omlonti® (omidenepag isopropyl)* Santen	Prostaglandin E receptor 2 agonist	Reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	TBD
Pedmark® (sodium thiosulfate) [†] Fennec	Reducing agent	Reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors	September 27, 2022
Relyvrio™ (sodium phenylbutyrate/taurursodiol) ^{*†} Amylyx	Neuroprotective	Treatment of amyotrophic lateral sclerosis in adults	October 2022
Rolvedon™ (eflapegrastim-xnst)* Spectrum	Granulocyte colony- stimulating factor	Decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving	Fourth Quarter of 2022

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
		myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia	
Skysona [®] (elivaldogene autotemcel) ^{††} bluebird bio	Gene therapy	Slow the progression of neurologic dysfunction in boys 4 to 17 years of age with early, active cerebral adrenoleukodystrophy (CALD)	September 22, 2022
Sotyktu [™] (deucravacitinib) [*] Bristol Myers Squibb	Tyrosine kinase 2 inhibitor	Treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy	September 13, 2022
Spevigo [®] (spesolimab-sbzo) ^{†*} Boehringer Ingelheim	IL-36 receptor antibody	Treatment of generalized pustular psoriasis flares in adults	September 5, 2022
Terlivaz [®] (terlipressin) ^{†*} Mallinckrodt	Vasopressin analogue	Improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function	October 2022

*New molecular entity; †Orphan drug

New biosimilars

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Stimufend [®] (pegfilgrastim-fpgk) Fresenius Kabi	Hematological Agents	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	TBD
Vegzelma [®] (bevacizumab-adcd) Celltrion USA	Antineoplastics & Adjunctive Therapies	Metastatic colorectal cancer; First-line non-squamous non-small cell lung cancer; Recurrent glioblastoma; Metastatic renal cell carcinoma; Persistent, recurrent, or metastatic cervical cancer, and Epithelial ovarian, fallopian tube, or primary peritoneal cancer	TBD

TBD: to be determined

New generics

Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Divigel® (estradiol) Vertical	Xiromed/Chemo ^{†±}	0.1% transdermal gel	Treatment of moderate to severe vasomotor symptoms due to menopause	September 27, 2022
Pradaxa® (dabigatran etexilate) Boehringer Ingelheim	Ascend/Alkem [†] , Camber/Hetero [†]	Ascend: 75 mg capsules, Camber: 75 mg and 150 mg capsules	Reduce the risk of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation; Treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in adult patients who have been treated with a parenteral anticoagulant for 5-10 days; Reduce the risk of recurrence of DVT and PE in adult patients who have been previously treated; Prophylaxis of DVT and PE, in adult patients who have undergone hip replacement surgery; Treatment of venous thromboembolic events (VTE) in pediatric patients 8 to less than 18 years of age who have been treated with a parenteral anticoagulant for at least 5 days; Reduce the risk of recurrence of VTE in pediatric patients 8 to less than 18 years of age who have been previously treated.	June 27, 2022* September 1, 2022 [‡] , September 6, 2022 [‡]
Tazorac® (tazarotene) Allergan	Cosette ^{†±}	0.05%, 0.1% gel	Plaque psoriasis and facial acne vulgaris of mild to moderate severity	September 15, 2022

[†]A-rated generic manufacturer; [±]Granted 180 days marketing exclusivity, *Launch date for Ascend; [‡]Launch date for Camber,

New authorized brand alternatives

Drug name manufacturer(s)	Authorized brand alternative manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Tresiba [®] (insulin degludec) Novo Nordisk	Novo Nordisk	100 units/mL, 200 units/mL	To improve glycemic control in patients with diabetes mellitus	Fall 2022

Indications/Label updates

Drug name manufacturer(s)	Type	Description
Dupixent [®] (dupilumab) Sanofi and Regeneron	New indication	Treatment of adult patients with prurigo nodularis
Firdapse [®] (amifampridine) Catalyst	Expanded indication	Treatment of Lambert-Eaton myasthenic syndrome in adults and pediatric patients 6 years of age and older
Imfinzi [®] (durvalumab) AstraZeneca	New orphan indication	In combination with gemcitabine and cisplatin, for the treatment of adult patients with locally advanced or metastatic biliary tract cancer
Orkambi [®] (lumacaftor/ivacaftor) Vertex	Expanded indication, new strength	Treatment of cystic fibrosis (CF) in patients aged 1 year and older who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene In addition to the expanded indication, a new dosage strength of the oral granules was approved (lumacaftor 75 mg/ivacaftor 94 mg unit-dose packets).
Retevmo [®] (selpercatinib) Eli Lilly	New indication	Treatment of adult patients with locally advanced or metastatic solid tumors with a rearranged during transfection gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options

Drug name manufacturer(s)	Type	Description
Zejula® (niraparib) GlaxoSmithKline	Indication removal	The FDA approved an indication removal for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with 3 or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency positive status defined by either: a deleterious or suspected deleterious BRCA mutation, or genomic instability and who have progressed more than 6 months after response to the last platinum-based chemotherapy

Drug safety news / Drug updates

Drug name manufacturer(s)	Description
AMX-0035 (sodium phenylbutyrate/taurursodiol) Amylyx Pharmaceuticals	The FDA convened a second Peripheral and Central Nervous System (PCNS) Drugs Advisory Committee meeting to discuss AMX-0035 for the treatment of amyotrophic lateral sclerosis.
COVID-19 vaccines Pfizer/BioNTech and Moderna	The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices recommended a booster dose of Moderna COVID-19 vaccine, bivalent for individuals 18 years of age and older and Pfizer COVID-19 vaccine, bivalent for individuals 12 years of age and older, under the emergency use authorization issued by the FDA
Lecanemab Biogen and Eisai	Biogen and Eisai announced positive topline results from the Phase 3 confirmatory Clarity AD trial of lecanemab, for the treatment of mild cognitive impairment (MCI) due to Alzheimer's disease (AD) and mild AD. Eisai will present the full Clarity AD study results on November 29, 2022, at the Clinical Trials on Alzheimer's Congress.

Drug recalls/Withdrawals/Shortages/Discontinuations

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Atenolol and clopidogrel Golden State Medical Supply	atenolol: 25 mg tablets clopidogrel: 75 mg tablets	Recall	<p>Golden State Medical Supply announced a voluntary consumer-level recall of one lot of atenolol 25 mg tablets and one lot of clopidogrel 75 mg tablets because a report was received that a bottle containing clopidogrel was mislabeled as atenolol.</p> <p>Atenolol tablets are indicated for the treatment of hypertension, long-term management of patients with angina pectoris, and in the management of hemodynamically stable patients with definite or suspected acute myocardial infarction (MI) to reduce cardiovascular mortality.</p> <p>Clopidogrel is indicated to reduce the rate of MI and stroke in patients with non-ST-segment elevation ACS (unstable angina [UA]/non-ST-elevation MI [NSTEMI]), including patients who are to be managed medically and those who are to be managed with coronary revascularization; and to reduce the rate of MI and stroke in patients with acute STEMI who are managed medically.</p> <p>Clopidogrel is also indicated to reduce the rate of MI and stroke in patients with established peripheral arterial disease or with a history of recent MI or recent stroke.</p>
Acyclovir Eugia	50 mg/mL injection	Recall	<p>Eugia announced a voluntary recall of one lot of acyclovir sodium injection to the consumer level due to a product complaint for the presence of a dark red, brown and black particulate inside the vial.</p> <p>Acyclovir injection is indicated for the treatment of herpes simplex infections in immunocompromised patients, initial episodes of herpes genitalis, herpes simplex encephalitis, neonatal herpes infections, and varicella-zoster infections in immunocompromised patients.</p>
Aminophylline Pfizer	25 mg/mL injection	Recall	<p>Pfizer announced a voluntary recall of one lot of aminophylline injection to the user level due to a confirmed report of a visible particulate observed in a single vial.</p> <p>Aminophylline injection is indicated as an adjunct to inhaled beta-2 selective agonists and systemically administered corticosteroids for the treatment of acute exacerbations of the symptoms and reversible airflow obstruction associated with asthma and other chronic lung diseases, e.g., emphysema and chronic bronchitis.</p>

Key guideline/Literature updates

Topic	Reference
National Institutes of Health – COVID-19 Treatment	<u>COVID-19 Treatment Guidelines</u> . September 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bone Cancer - Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Bone Cancer</u> . September 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Central Nervous System Cancers - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Central Nervous System Cancers</u> . September 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers - Version 4.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers</u> . September 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma</u> . September 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kidney Cancer - Version 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer</u> . September 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma</u> . September 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes</u> . September 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer - Version 5.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer</u> . September 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer - Version 5.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer</u> . September 2022

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Aggressive Mature B-Cell Lymphomas - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Aggressive Mature B-Cell Lymphomas.</u> September 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: .</u> September 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer.</u> September 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer.</u> September 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening - Version 3.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening.</u> September 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic.</u> September 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation.</u> September 2022



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