

RxHighlights

August 2022

New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Auvelity™ (dextromethorphan/bupropion) Axsome Therapeutics	N-methyl-D-aspartate antagonist and aminoketone/CYP450 2D6 inhibitor	Treatment of major depressive disorder in adults	Fourth quarter 2022
Calquence® (acalabrutinib)*† 100 mg tablet AstraZeneca	Bruton's tyrosine kinase inhibitor	Treatment of adult patients with mantle cell lymphoma who have received at least one prior therapy, and for the treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma	August 10, 2022
Konvomep™ (omeprazole/sodium bicarbonate) Azurity Pharmaceuticals	Proton pump inhibitor/ antacid	In adults for: short-term treatment (4 to 8 weeks) of active benign gastric ulcer and reduction of risk of upper gastrointestinal bleeding in critically ill adult patients.	September 2022
Xenpozyme™ (olipudase alfa-rpcp)* Sanofi	Enzyme replacement therapy	Treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency in adult and pediatric patients	September 7, 2022
Zynteglo® (betibeglogene autotemcel)* bluebird bio	Gene therapy	Treatment of adult and pediatric patients with β -thalassemia who require regular red blood cell transfusions	August 25, 2022

*New molecular entity; †Orphan drug

New biosimilars

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Cimerli™ (ranibizumab-eqrn)* Coherus Biosciences	Vascular endothelial growth factor inhibitor	Treatment of patients with neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, and myopic choroidal neovascularization	Early October 2022
Hadlima™ (adalimumab-bwwd) 100 mg/mL injection Samsung Bioepis, Organon	Tumor necrosis factor	Rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult and pediatric Crohn's disease, ulcerative colitis, and plaque psoriasis	July 1, 2023

* Interchangeable to Lucentiz® (ranibizumab)

Indications/Label updates

Drug name manufacturer(s)	Type	Description
COVID-19 vaccines Moderna, Pfizer/BioNTech	Emergency use authorization (EUA)	The FDA announced the emergency use authorization of two new updated COVID-19 vaccines: Moderna's COVID-19 vaccine, bivalent (Original and Omicron BA.4/BA.5) and Pfizer/BioNTech's COVID-19 vaccine, bivalent (Original and Omicron BA.4/BA.5). Both vaccines are authorized for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
COVID-19 vaccine, adjuvanted Novavax	Expanded EUA	The FDA announced the EUA of the Novavax COVID-19 vaccine, adjuvanted, for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older
Enhertu® (fam-trastuzumab deruxtecan-nxki) Astra Zeneca, Daiichi Sankyo	New indications	Treatment of adult patients with unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-low (immunohistochemistry [IHC] 1+ or IHC 2+/- in situ hybridization [ISH]-) breast cancer who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy.

Drug name manufacturer(s)	Type	Description
		Treatment of adult patients with unresectable or metastatic non-small cell lung cancer whose tumors have activating HER2 mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy.
Imbruvica [®] (ibrutinib) J&J, AbbVie	Expanded indication, new formulation approval	Treatment of adult and pediatric patients age 1 year and older with chronic graft-versus-host disease after failure of one or more lines of systemic therapy J&J and AbbVie also announced the approval of a new oral suspension formulation of Imbruvica (70 mg/mL) to support the expanded indication.
Jynneos [®] (smallpox and monkeypox vaccine, live, nonreplicating) Bavarian Nordic	EUA	Active immunization by subcutaneous injection for prevention of monkeypox disease in individuals less than 18 years of age determined to be at high risk for monkeypox infection, and for active immunization by intradermal injection for prevention of monkeypox disease in individuals 18 years of age and older determined to be at high risk for monkeypox infection
Lynparza [®] (olaparib) AstraZeneca	Indication withdrawal	Treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy
Mirena [®] (levonorgestrel-releasing intrauterine system) Bayer Healthcare	Expanded indication	Prevention of pregnancy for up to 8 years; replace after the end of the eighth year
Myfembree [®] (relugolix/estradiol/norethindrone acetate) Pfizer	New indication	Premenopausal women for the management of moderate to severe pain associated with endometriosis
Nubeqa [®] (darolutamide) Bayer	Expanded indication	Treatment of adult patients with metastatic hormone-sensitive prostate cancer in combination with docetaxel
Pemazyre [®] (pemigatinib) Incyte	New indication	Treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms with fibroblast growth factor receptor 1 rearrangement
Rebiny [®] (Coagulation Factor IX (Recombinant), GlycoPEGylated)	Expanded indication	For use in adults and children with hemophilia B (congenital Factor IX deficiency) for routine prophylaxis to reduce the frequency of bleeding episodes

Drug name manufacturer(s)	Type	Description
Novo Nordisk		
Xofluza® (baloxavir marboxil) Genentech	Expanded indications	Treatment of acute uncomplicated influenza in patients who have been symptomatic for no more than 48 hours and who are otherwise healthy adults and pediatric patients 5 years of age and older

Drug recalls/Withdrawals/Shortages/Discontinuations

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Magnesium citrate saline laxative Vi-Jon	Various oral solution products	Recall	Vi-Jon announced a revision to the voluntary consumer-level recall of various brands of magnesium citrate saline laxative oral solution products to include product that was distributed in the U.S., Canada and Panama. This recall includes all lots of cherry and grape flavors within expiry because they contain <i>Gluconacetobacter liquefaciens</i> . Magnesium citrate saline laxative is used for relief of occasional constipation.
Magnesium hydroxide/aluminum hydroxide/simethicone Plastikon Healthcare	Magnesium hydroxide 1200 mg/ aluminum hydroxide 1200 mg/ simethicone 120 mg per 30 mL oral solution	Recall	The FDA announced an update to the voluntarily consumer-level recall of Plastikon Healthcare's magnesium hydroxide/aluminum hydroxide/simethicone initiated on June 3, 2022 to include an additional lot. The recall is due to microbial contamination. Magnesium hydroxide/aluminum hydroxide/simethicone is indicated for relief of acid indigestion, heartburn, sour stomach, upset stomach due to these symptoms, pressure and bloating commonly referred to as gas.
Glucerna® Original, Ensure Harvest™ and PediaSure Harvest™ Abbott	Various products and package sizes	Recall	Abbott announced a voluntary recall of certain nutritional and beverage products due to the potential for microbial contamination. The recall is an expansion of a recall announced by Lyons Magnus on July 29, 2022. Glucerna Original is designed as a snack or meal replacement to help minimize blood sugar spikes compared to high-glycemic carbohydrates. Ensure Harvest and PediaSure Harvest are

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
			nutritional products used for tube feedings. Ensure Harvest can be used with bolus syringe, gravity syringe and pump-assisted feeding. PediaSure can also be used for oral feedings.
Various nutritional and beverage products Lyons Magnus	Various products and package sizes	Recall	Lyons Magnus announced a voluntary recall of nutritional and beverage products due to the potential for microbial contamination,. The recall is an expansion of a recall announced July 29, 2022.

Key guideline/Literature updates

Topic	Reference
Management of Hyperbilirubinemia in the Newborn Infant \geq 35 Weeks of Gestation – American Academy of Pediatrics	<i>Pediatrics</i> . August 2022
Management of Hyperglycemia in Hospitalized Adult Patients in Non-Critical Care Settings – Endocrine Society	<i>Journal of Clinical Endocrinology and Metabolism</i> . June 2022
Monkeypox and Smallpox Vaccine Guidance – Centers for Disease Control and Prevention	<i>Centers for Disease Control and Prevention</i> . August 2022
National Institutes of Health – COVID-19 Treatment	<i>COVID-19 Treatment Guidelines</i> . August 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma - Version 1.2023	<i>NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma</i> . August 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia - Version 1.2023	<i>NCCN Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia</i> . August 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms - Version 3.2022	<i>NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms</i> . August 2022

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer - Version 4.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer.</u> August 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer.</u> August 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Vulvar Cancer - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Vulvar Cancer.</u> August 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening.</u> August 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prevention and Treatment of Cancer-Related Infections - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Prevention and Treatment of Cancer-Related Infections.</u> August 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Smoking Cessation - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Smoking Cessation.</u> August 2022



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