

# RxHighlights

March 2023

## New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Combogesic<sup>®</sup></b> (acetaminophen/ibuprofen) AFT	Non-salicylate analgesic/ nonsteroidal anti- inflammatory drug	Short-term management of mild to moderate acute pain	TBD
<b>Daybue<sup>™</sup></b> (trofinetide) <sup>†*</sup> Acadia	Insulin-like growth factor 1 derivative	Treatment of Rett syndrome in adults and pediatric patients 2 years of age and older	April 2023
<b>Joenja<sup>®</sup></b> (leniolisib) <sup>†*</sup> Pharming	Phosphatidylinositol- 3-4-5-trisphosphate inhibitor	Treatment of activated phosphoinositide 3-kinase delta syndrome in adult and pediatric patients 12 years of age and older	April 2023
<b>Naloxone nasal spray</b> Amphastar	Opioid antagonist	Emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, for adult and pediatric patients	TBD
<b>Narcan<sup>®</sup></b> (naloxone) 4 mg nasal spray <sup>‡</sup> Emergent BioSolutions	Opioid antagonist	Emergency treatment of opioid overdose (from prescription pain medications or street drugs such as heroin).	Late Summer 2023
<b>Rezzayo<sup>™</sup></b> (rezafungin) <sup>†*</sup> Cidara, Melinta	Echinocandin	Patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis	Summer 2023
<b>Skyclarys<sup>™</sup></b> (omaveloxolone) <sup>†*</sup> Reata	Nrf2 pathway activator	Treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older	Second Quarter 2023

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Zavzpret™</b> (zavegepant)* Pfizer	Calcitonin gene-related peptide receptor antagonist	Acute treatment of migraine with or without aura in adults	July 2023
<b>Zynyz™</b> (retifanlimab-dlwr) <sup>†*</sup> Incyte	Programmed cell death protein 1 inhibitor	Treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma	TBD

\*New molecular entity; †Orphan drug; ±New prescription to over-the-counter approval; TBD: To be determined

### New biosimilars

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Hyrimoz®</b> (adalimumab-adaz) citrate-free, high concentration (100 mg/mL) injection Sandoz	Analgesics & Anesthetics	Rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult and pediatric Crohn's disease, ulcerative colitis, and plaque psoriasis	July 1, 2023

### New generics

Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
<b>Aubagio®</b> (teriflunomide) Genzyme	Zydus <sup>†</sup> , Accord <sup>†</sup> , Dr. Reddy's <sup>†</sup> , Aurobindo <sup>†</sup> , Glenmark <sup>†</sup> , Teva <sup>†</sup> , Sandoz <sup>†</sup> , Viatris <sup>†</sup> and Camber <sup>†</sup>	7 mg, 14 mg tablet	Treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults	March 13, 2023

Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
<b>Pylera</b> <sup>®</sup> (bismuth subcitrate potassium/metronidazole/tetracycline) AbbVie	Par <sup>†</sup>	bismuth subcitrate potassium 140 mg, metronidazole 125 mg, tetracycline 125 mg capsule	In combination with omeprazole for the treatment of patients with <i>Helicobacter pylori</i> ( <i>H. pylori</i> ) infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate <i>H. pylori</i> .	March 10, 2023

<sup>†</sup>A-rated generic manufacturer

### New authorized brand alternatives

Drug name manufacturer(s)	Authorized brand alternative manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
<b>Advair HFA</b> <sup>®</sup> (fluticasone/salmeterol) GSK	Prasco	45 mcg/21 mcg, 115 mcg/21mcg, 230 mcg/21 mcg oral inhalation	Treatment of asthma in adult and adolescent patients aged 12 years and older	March 1, 2023
<b>Firvanq</b> <sup>®</sup> Kit (vancomycin) Azurity	Wilshire	25 mg, 50 mg oral solution	Adults and pediatric patients less than 18 years of age for the treatment of <i>Clostridium difficile</i> -associated diarrhea and for the treatment of enterocolitis caused by <i>Staphylococcus aureus</i> (including methicillin-resistant strains)	March 29, 2023

## Indications/Label updates

Drug name manufacturer(s)	Type	Description
<b>Evkeeza</b> <sup>®</sup> (evinacumab-dgnb) Regeneron	Expanded indication	Adjunct to other low-density lipoprotein-cholesterol lowering therapies for the treatment of adult and pediatric patients, aged 5 years and older, with homozygous familial hypercholesterolemia
<b>Kevzara</b> <sup>®</sup> (sarilumab) Regeneron and Sanofi	New indication	Treatment of adult patients with polymyalgia rheumatica who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper
<b>Livmarli</b> <sup>®</sup> (maralixibat) Mirum	Expanded indication	Treatment of cholestatic pruritus in patients with Alagille syndrome 3 months of age and older
<b>Tafinlar</b> <sup>®</sup> (dabrafenib) plus <b>Mekinist</b> <sup>®</sup> (trametinib) Novartis	New indication, new formulation	Treatment of pediatric patients 1 year of age and older with low-grade glioma with a BRAF V600E mutation who require systemic therapy
<b>Verzenio</b> <sup>®</sup> (abemaciclib) Eli Lilly	Expanded indication	In combination with endocrine therapy (tamoxifen or an aromatase inhibitor), for the adjuvant treatment of adult patients with hormone receptor positive, human epidermal growth factor receptor 2 negative, node-positive, early breast cancer at high risk of recurrence. This expanded indication removes the previous Ki-67 score requirement for patient selection.

## Drug safety news / Drug updates

Drug name manufacturer(s)	Description
<b>Pfizer/BioNTech COVID-19 vaccine, bivalent</b> Pfizer/BioNTech	The FDA amended the emergency use authorization (EUA) of the Pfizer/BioNTech COVID-19 vaccine, bivalent to provide for a single booster dose of the vaccine in children 6 months through 4 years of age at least 2 months after completion of primary vaccination with three doses of the monovalent (single strain) Pfizer/BioNTech COVID-19 vaccine.
<b>Leqembi™</b> (lecanemab-irmb) Eisai and Biogen	Eisai and Biogen announced that the FDA has accepted their supplemental Biologics License Application for Leqembi, requesting the conversion of the accelerated approval of Leqembi to a traditional (full) approval. The Leqembi application has been granted Priority Review, with a Prescription Drug User Fee Act action date of July 6, 2023.
<b>Paxlovid™</b> (nirmatrelvir/ritonavir) Pfizer	The FDA's Antimicrobial Drugs Advisory Committee recommended (16 yes and 1 no) that Paxlovid has a favorable benefit-risk assessment when used for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death.

## Drug recalls/Withdrawals/Shortages/Discontinuations

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
<b>Aprepitant</b> Sandoz	125 mg capsules	Recall	Sandoz announced a consumer level recall of two lots of aprepitant capsules because the packaging is not child-resistant as required by the Poison Prevention Packaging Act, posing a risk of harm if children ingest the drugs.  Aprepitant is indicated for the prevention of chemotherapy induced nausea and vomiting and for the prevention of postoperative nausea and vomiting.
<b>Atovaquone</b> Camber	750 mg/5 mL oral suspension	Recall	Camber announced a consumer-level recall of one lot of atovaquone oral suspension due to potential <i>Bacillus cereus</i> contamination in the product.

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			Atovaquone is indicated for the treatment and prevention of <i>Pneumocystis jirovecii</i> pneumonia.
<b>Brimonidine tartrate</b> Apotex	0.15% ophthalmic solution	Recall	Apotex announced a consumer-level recall of six lots of brimonidine tartrate ophthalmic solution due to cracks that have developed in some of the units caps of bottles that may impact sterility and if so, the possibility of adverse events.  Brimonidine ophthalmic solution indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.
<b>Dabigatran</b> Ascend	75 mg, 150 mg capsules	Recall	Ascend announced a consumer-level recall of dabigatran capsules due to the presence of a nitrosamine, N-nitroso-dabigatran, above the established FDA acceptable daily intake level.  Dabigatran is used as an oral anticoagulant to lower the risk of stroke and blood clots.
<b>Lidocaine/prilocaine</b> Sandoz	2.5%/2.5% cream	Recall	Sandoz announced a consumer level recall of nine lots of lidocaine/prilocaine cream because the packaging is not child-resistant as required by the Poison Prevention Packaging Act, posing a risk of harm if children ingest the drugs or put the cream on their skin.  Lidocaine and prilocaine cream is indicated as a topical anesthetic for use on normal intact skin for local analgesia and for use on genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia.
<b>Nurtec® ODT</b> (rimegepant) Pfizer	75 mg orally disintegrating tablets	Recall	Pfizer announced a consumer-level recall of Nurtec ODT 75 mg orally disintegrating tablets sold in cartons containing one blister card of 8 tablets because the tablets are in a non-child resistant blister card.

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
			Nurtec ODT is indicated for the acute treatment of migraine with or without aura in adults and for the preventive treatment of episodic migraine in adults.

### Key guideline/Literature updates

Topic	Reference
American College of Gastroenterology – Management of Celiac Disease	<a href="#"><i>American Journal of Gastroenterology</i></a> . February 2023
American College of Gastroenterology - Diagnosis and Management of Biliary Strictures	<a href="#"><i>American Journal of Gastroenterology</i></a> . March 2023
American Society of Transplantation and Cellular Therapy - Blood and Marrow Transplantation in Children with Malignancies	<a href="#"><i>Transplantation and Cellular Therapy</i></a> . February 2023
American Society of Colon and Rectal Surgeons – Anal Fissure	<a href="#"><i>Diseases of the Colon &amp; Rectum</i></a> . February 2023
American Society of Colon and Rectal Surgeons – Fecal Incontinence	<a href="#"><i>Diseases of the Colon &amp; Rectum</i></a> . February 2023
Endocrine Society – Hypercalcemia of Malignancy	<a href="#"><i>JAMA Oncology</i></a> . January 2023
National Institutes of Health – COVID-19 Treatment	<a href="#"><i>COVID-19 Treatment Guidelines</i></a> . March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia - Version 2.2023	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia</i></a> . March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer - Version 1.2023	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer</i></a> . March 2023

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Biliary Tract Cancers - Version 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Biliary Tract Cancers.</u></a> March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer - Version 4.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer.</u></a> March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Central Nervous System Cancers - Version 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Central Nervous System Cancers.</u></a> March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer - Version 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer.</u></a> March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers - Version 2.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers.</u></a> March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastric Cancer - Version 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer.</u></a> March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastrointestinal Stromal Tumors - Version 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Gastrointestinal Stromal Tumors.</u></a> March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatocellular Carcinoma - Version 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Hepatocellular Carcinoma.</u></a> March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous - Version 2.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous.</u></a> March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia - Version 2.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia.</u></a>



Topic	Reference
	March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Hodgkin Lymphoma - Version 2.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Hodgkin Lymphoma.</u></a> March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer - Version 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer.</u></a> March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma - Version 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma.</u></a> March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Squamous Cell Skin Cancer - Version 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Squamous Cell Skin Cancer.</u></a> March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thyroid Carcinoma - Version 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma.</u></a> March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Wilms Tumor (Nephroblastoma) - Version 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Wilms Tumor (Nephroblastoma).</u></a> March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adult Cancer Pain - Version 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain.</u></a> March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer-Associated Venous Thromboembolic Disease - Version 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Cancer-Associated Venous Thromboembolic Disease.</u></a> March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation - Version 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation.</u></a> March 2023

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors - Version 2.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors.</u></a> March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities - Version 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities.</u></a> March 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Survivorship - Version 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Survivorship.</u></a> March 2023
Pediatric Acute Respiratory Distress Syndrome - Pediatric Acute Lung Injury Consensus Conference	<a href="#"><u>Pediatric Critical Care Medicine.</u></a> February 2023

