

# RxHighlights

May 2023

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## New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Abrysvo™</b> (respiratory syncytial virus vaccine) Pfizer	Vaccine	Active immunization for the prevention of lower respiratory tract disease caused by respiratory syncytial virus in individuals 60 years of age and older	3Q 2023
<b>Arexvy</b> (respiratory syncytial virus vaccine, adjuvanted) GSK	Vaccine	Active immunization for the prevention of lower respiratory tract disease caused by respiratory syncytial virus in individuals 60 years of age and older	Before the 2023/2024 RSV season
<b>Brixadi™</b> (buprenorphine) Braebum	Opioid receptor agonist (partial)	Treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine	September 2023
<b>Elfabrio®</b> (pegunigalsidase alfa-iwxj)* Chiesi Global Rare Diseases, Protalix BioTherapeutics	Enzyme replacement therapy	Treatment of adults with confirmed Fabry disease	May 19, 2023
<b>Epkinly™</b> (epcoritamab-bysp)* AbbVie	CD3/CD20 monoclonal antibody	Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy	May 26, 2023

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Inpefa</b> <sup>®</sup> (sotagliflozin)* Lexicon	Sodium-dependent glucose transporter 1 (SGLT-1) and SGLT- 2 inhibitor	Reduce the risk of cardiovascular (CV) death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure; or type 2 diabetes mellitus, chronic kidney disease, and other CV risk factors	June 2023
<b>Lumryz</b> <sup>™</sup> (sodium oxybate) <sup>†</sup> Avadel	Dopamine receptor agonist	Treatment of cataplexy or excessive daytime sleepiness in adults with narcolepsy	May 9, 2023
<b>Miebo</b> <sup>™</sup> (perfluorohexyloctane)* Bausch & Lomb	Tear film stabilizer	Treatment of the signs and symptoms of dry eye disease	Second half of 2023
<b>Motpoly XR</b> (lacosamide) Acute Pharmaceuticals	Antiepileptic	Treatment of partial-onset seizures in adults and in pediatric patients weighing at least 50 kg	TBD
<b>Opvee</b> <sup>®</sup> (nalmeфene) Indivior	Opioid receptor antagonist	Emergency treatment of known or suspected overdose induced by natural or synthetic opioids in adults and pediatric patients aged 12 years and older, as manifested by respiratory and/or central nervous system depression	Fourth quarter 2023
<b>Paxlovid</b> <sup>®</sup> (nirmatrelvir; ritonavir)* Pfizer	Protease inhibitor	Treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults who are at high risk for progression to severe COVID-19, including hospitalization or death	December 27, 2021
<b>Symbicort Aerosphere</b> <sup>®</sup> (budesonide/formoterol) AstraZeneca	Corticosteroid/ long- acting beta2- adrenergic agonist	Maintenance treatment of patients with chronic obstructive pulmonary disease	TBD
<b>Xacduro</b> <sup>®</sup> (sulbactam; durlobactam)* Innoviva Specialty Therapeutics	Broad-spectrum $\beta$ - lactamase inhibitor/ beta-lactam antimicrobial	Treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia, caused by susceptible isolates of <i>Acinetobacter baumannii-calcoaceticus</i> complex in patients 18 years of age and older	TBD
<b>Veozah</b> <sup>™</sup> (fezolinetant)* Astellas	Neurokinin 3 receptor antagonist	Treatment of moderate to severe vasomotor symptoms due to menopause	May 17, 2023

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Vevye</b> (cyclosporine) Novaliq	Immunosuppressant	Treatment of the signs and symptoms of dry eye disease	TBD
<b>Vyjuvek™</b> (beremagene geperpavec-svdt) †* Krystal Biotech	Gene therapy	Treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa with mutation(s) in the <i>collagen type VII alpha 1 chain</i> gene	June 1, 2023

\*New molecular entity; †Orphan drug; TBD: To be determined

**New biosimilars**

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Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Yuflyma®</b> (adalimumab-aaty) 40 mg/0.4 mL prefilled syringe and 40 mg/0.4 mL auto-injector Celltrion	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

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## New generics

Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
<b>Celontin</b> <sup>®</sup> (methsuximide) Pfizer	ANI Pharmaceuticals <sup>±</sup>	300 mg capsules	Control of absence (petit mal) seizures that are refractory to other drugs	May 15, 2023
<b>Iressa</b> <sup>®</sup> (gefitinib) AstraZeneca	Ingenus <sup>†</sup> , Apotex <sup>†</sup> and Actavis/Teva <sup>†</sup>	250 mg tablets	Metastatic non-small cell lung cancer	May 3, 2023 <sup>^</sup>

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

<sup>^</sup>Launch date for Ingenus; Launch dates for Apotex and Actavis/Teva are to be determined

<sup>±</sup>Granted 180-days of competitive generic therapy exclusivity

## Indications/Label updates

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Drug name manufacturer(s)	Type	Description
<b>Ayvakit</b> <sup>®</sup> (avapritinib) Blueprint Medicines	New orphan indication	Treatment of adult patients with indolent systemic mastocytosis
<b>Breo Ellipta</b> <sup>®</sup> (fluticasone furoate/vilanterol) GSK	Expanded indication, new strength	Maintenance treatment of asthma in patients aged 5 years and older  To support the expanded indication, the FDA approved a new lower dosage strength of Breo Ellipta (50 mcg fluticasone furoate and 25 mcg vilanterol per actuation).
<b>Caldolor</b> <sup>®</sup> (ibuprofen) Cumberland	Expanded indication	In adults and pediatric patients aged 3 months and older for the management of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics; reduction of fever

Drug name manufacturer(s)	Type	Description
<b>Farxiga</b> <sup>®</sup> (dapagliflozin) AstraZeneca	Expanded indication	To reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure
<b>Injectafer</b> <sup>®</sup> (ferric carboxymaltose) Daiichi Sankyo	New indication	Treatment of iron deficiency in adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity
<b>Imbruvica</b> <sup>®</sup> (ibrutinib) Janssen	Indication and strength removals	<p>The FDA approved revisions to the Imbruvica label to voluntarily remove the following indications treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy; and treatment of adult patients with marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy</p> <p>In addition to the indication removals, the FDA also approved the removal of the Imbruvica 560 mg tablet. This strength was specifically approved for MCL and MZL.</p>
<b>Kalydeco</b> <sup>®</sup> (ivacaftor) Vertex	Expanded indication, new dosage strengths	<p>Treatment of cystic fibrosis in patients age 1 month and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator gene that is responsive to ivacaftor potentiation based on clinical and/or <i>in vitro</i> assay data</p> <p>To support the expanded indication, the FDA approved 5.8 mg and 13.4 mg Kalydeco oral granules.</p>
<b>Lexapro</b> <sup>®</sup> (escitalopram) AbbVie	Expanded indication	Treatment of generalized anxiety disorder in adults and pediatric patients 7 years of age and older
<b>Rexulti</b> <sup>®</sup> (brexpiprazole) Otsuka and Lundbeck	New indication	Treatment of agitation associated with dementia due to Alzheimer's disease
<b>Rinvoq</b> <sup>®</sup> (upadacitinib) AbbVie	New indication	Treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more tumor necrosis factor blockers

Drug name manufacturer(s)	Type	Description
<b>Zinplava™</b> (bezlotoxumab) Merck	Expanded indication	Reduce recurrence of <i>Clostridioides difficile</i> infection (CDI) in adults and pediatric patients 1 year of age and older who are receiving antibacterial drug treatment for CDI and are at a high risk for CDI recurrence

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**Drug recalls/Withdrawals/Shortages/Discontinuations**

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
<b>Antibiotic injectable products</b> Astral SteriTech	Ampicillin for injection; ampicillin/ sulbactam for injection; cefepime for injection; ceftriaxone for injection; and piperacillin/tazobactam for injection	Recall	Astral SteriTech announced a user-level recall of all sterile antibiotic powders for injection because of quality concerns at its manufacturing facility. The sterility of these products cannot be assured
<b>G-Supress DX Pediatric Drops</b> Novis PR	Dextromethorphan/ guaifenesin/ phenylephrine pediatric drops	Recall	Novis PR announced a voluntary consumer-level recall of one lot of G-Supress DX Pediatric Drops because some cartons of the product have been found to contain incorrect product inside. Incorrect product inside is an anesthetic/analgesic and not a brand of Novis PR.  G-Supress DX Pediatric Drops is an over-the-counter cough suppressant, expectorant and nasal decongestant used for the temporarily relief of the common cold symptoms.

## Key guideline/Literature updates

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia Version - 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia.</u></a> May 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas Version - 3.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas.</u></a> May 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Biliary Tract Cancers Version - 2.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Biliary Tract Cancers.</u></a> May 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer Version - 3.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer.</u></a> May 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Head and Neck Cancers Version - 2.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers.</u></a> May 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Melanoma: Uveal Version - 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Melanoma: Uveal.</u></a> May 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Version - 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions.</u></a> May 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms Version - 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms.</u></a> May 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma Version - 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma.</u></a> May 2023

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer Version - 3.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer.</u></a> May 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Systemic Mastocytosis Version - 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Systemic Mastocytosis.</u></a> May 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thyroid Carcinoma Version - 2.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma.</u></a> May 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening Version - 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening.</u></a> May 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal Version - 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal.</u></a> May 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Lung Cancer Screening Version - 2.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Lung Cancer Screening.</u></a> May 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Antiemesis Version - 2.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Antiemesis.</u></a> May 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities Version - 2.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities.</u></a> May 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Smoking Cessation Version - 1.2023	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Smoking Cessation.</u></a> May 2023



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