

RxHighlights

November 2023

[Learn more](#)

New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Adzynma (ADAMTS13, recombinant-krhn)*† tablets Takeda	ADAMTS13 enzyme	Prophylactic or on demand enzyme replacement therapy in adult and pediatric patients with congenital thrombotic thrombocytopenic purpura	November 29, 2023
Alvaiz™ (eltrombopag) Teva	Thrombopoietin receptor agonist	Treatment of thrombocytopenia in adult and pediatric patients 6 years and older with persistent or chronic immune thrombocytopenia who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Alvaiz should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding; Thrombocytopenia in adult patients with chronic hepatitis C (CHC) to allow the initiation and maintenance of interferon-based therapy. Alvaiz should be used only in patients with CHC whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy; Adult patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy	TBD
Augtyro™ (repotrectinib)† Bristol Myers Squibb	Tyrosine kinase inhibitor	Treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer	November 27, 2023
Fruzaqla™ (fruquintinib)* Takeda	Kinase inhibitor	Treatment of adult patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-vascular endothelial growth factor therapy, and, if RAS wild-type and medically appropriate, an anti-epidermal growth factor receptor therapy	November 10, 2023

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Ixchiq [®] (chikungunya vaccine, live) Valneva	Vaccine	Prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years of age and older who are at increased risk of exposure to CHIKV	Early 2024
Ogsiveo [™] (nirogacestat) ^{††} SpringWorks Therapeutics	Gamma secretase inhibitor	Adult patients with progressing desmoid tumors who require systemic treatment	November 29, 2023
Ryzneuta [®] (efbemalenograstim alfa-vuxw) [*] Evive Biotechnology	Granulocyte colony- stimulating factor	To decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia	TBD
Truqap [™] (capivasertib) [*] AstraZeneca	Kinase inhibitor	In combination with fulvestrant, for the treatment of adult patients with hormone receptor positive, human epidermal growth factor receptor 2 negative, locally advanced or metastatic breast cancer with one or more <i>PIK3CA/AKT1/PTEN</i> -alterations as detected by an FDA-approved test following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy	November 20, 2023
Voquezna [®] (vonoprazan) Phathom Pharmaceuticals	Potassium- competitive acid blocker	For healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults; to maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults; in combination with amoxicillin and clarithromycin for the treatment of <i>Helicobacter pylori</i> (<i>H. pylori</i>) infection in adults; in combination with amoxicillin for the treatment of <i>H. pylori</i> infection in adults	November 7, 2023
Zepbound [™] (tirzepatide) Eli Lilly	Glucose-dependent insulinotropic polypeptide receptor and glucagon-like peptide-1 receptor agonist	Adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index of 30 kg/m ² or greater (obesity); 27 kg/m ² or greater (overweight) in the presence of at least one weight-related comorbid condition (eg, hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease)	November 10, 2023
Zituvimet (sitagliptin/metformin) Zydus Pharmaceuticals	Dipeptidyl peptidase- 4 inhibitor/ biguanide	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	TBD

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

[Learn more](#)

New generics

Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Carospir [®] (spironolactone) CMP Pharma	Amneal [†]	25 mg/mL oral suspension	Treatment of New York Heart Association Class III - IV heart failure; add-on therapy for the treatment of hypertension; and management of edema in adult cirrhotic patients	November 2, 2023
Forteo [®] (teriparatide) Eli Lilly	Apotex [†] , Teva [†]	600 mcg/2.4 mL single patient-use prefilled pen	Treatment of postmenopausal women with osteoporosis at high risk for fracture or who have failed or are intolerant to other therapies; To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture or who have failed or are intolerant to other therapies; and treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture or who have failed or intolerant to other therapies	November 20, 2023 [§]
Livalo [®] (pitavastatin) Eli Lilly and Kowa Pharmaceuticals	Aurobindo [†] , Viatris [†] , Teva/Orient [†] , Upsher-Smith/Sawai [†] , and Zydus [†]	2 mg, 4 mg tablets	Adjunct to diet to reduce low-density lipoprotein cholesterol in adults with primary hyperlipidemia and adults and pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia	November 2, 2023

[†]A-rated generic manufacturer

[§]Teva launch date TBD

[Learn more](#)

New authorized brand alternatives

Drug name manufacturer(s)	Authorized brand alternative manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Carospir® (spironolactone) CMP Pharma	Padagis	25 mg/mL oral suspension	Treatment of New York Heart Association Class III - IV heart failure; add-on therapy for the treatment of hypertension; and management of edema in adult cirrhotic patients	November 2, 2023
Flovent Diskus® (fluticasone propionate) GSK	Prasco	50 mcg, 100 mcg, and 250 mcg inhalation powder	Maintenance treatment of asthma as prophylactic therapy in patients aged 4 years and older	November 1, 2023
Forteo® (teriparatide) Eli Lilly	Prasco	600 mcg/2.4 mL single patient-use prefilled pen	Treatment of postmenopausal women with osteoporosis at high risk for fracture or who have failed or are intolerant to other therapies; To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture or who have failed or are intolerant to other therapies; and treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture or who have failed or intolerant to other therapies	November 20, 2023

[Learn more](#)

Indications/Label updates

Drug name manufacturer(s)	Type	Description
Keytruda® (pembrolizumab) Merck	New indication	In combination with gemcitabine and cisplatin, for the treatment of patients with locally advanced unresectable or metastatic biliary tract cancer
	Expanded indication	In combination with fluoropyrimidine-and platinum-containing chemotherapy, for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma
	Updated indication	In combination with trastuzumab, fluoropyrimidine-and platinum-containing chemotherapy, for the first-line treatment of patients with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 as determined by an FDA-approved test
Xtandi® (enzalutamide) Astellas and Pfizer	Expanded indication	Treatment of patients with non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis

[Learn more](#)

Drug safety news / Drug updates

Drug name manufacturer(s)	Description
CAR T cell therapy	<p>The FDA announced they are investigating the risk of serious risk of T-cell malignancy following BCMA-directed or CD19-directed autologous chimeric antigen receptor (CAR) T cell immunotherapies.</p> <p>The FDA has received reports of T-cell malignancies, including CAR-positive lymphoma, in patients who received treatment with BCMA- or CD19-directed autologous CAR T cell immunotherapies. Reports were received from clinical trials and/or postmarketing adverse event data sources.</p> <p>The FDA has determined that the risk of T-cell malignancies is applicable to all currently approved BCMA-directed and CD19-directed genetically modified autologous CAR T cell immunotherapies. T-cell malignancies have occurred in patients treated with several products in the class.</p>
Levetiracetam and clobazam products	<p>The FDA warned that the antiseizure medicines levetiracetam (Keppra[®], Keppra XR[®], Elepsia[™] XR, Spritam[®], and generics) and clobazam (Onfi[®], Sympazan[™], and generics), can cause a rare but serious reaction that can be life-threatening if not diagnosed and treated quickly called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).</p> <p>It may start as a rash but can quickly progress, resulting in injury to internal organs, the need for hospitalization, and even death. As a result, the FDA is requiring warnings about this risk to be added to the prescribing information and patient Medication Guides for these medicines.</p>
Wegovy[®] (semaglutide) Novo Nordisk	<p>At the American Heart Association annual Scientific Sessions in Philadelphia, Novo Nordisk presented the positive results of overweight or obesity and a prior cardiovascular event. This was a full presentation of the data that was previously announced, in summary form, in a Novo Nordisk press release. Novo Nordisk has filed for a label update of Wegovy to include an indication for risk reduction of major adverse cardiovascular events in adults with a BMI of ≥ 27 kg/m² and established cardiovascular disease based on data from the SELECT trial.</p>

Drug recalls/Withdrawals/Shortages/Discontinuations

[Learn more](#)

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Aliqopa® (copanlisib) Bayer	60 mg injection	Withdrawal	<p>Bayer announced that following discussions with the FDA, it will withdraw the Aliqopa New Drug Application for adult patients with relapsed follicular lymphoma who have received at least two prior systemic therapies. A confirmatory clinical trial did not meet the primary endpoint of progression-free survival benefit vs. standard immunotherapy.</p>
Levemir® (insulin detemir) Novo Nordisk	3 mL single use FlexPens and 10 mL multiple dose vials	Discontinuation	<p>Novo Nordisk recently announced the discontinuation of Levemir due to business reasons. The discontinuation is not due to any safety or efficacy issues.</p> <p>Levemir is indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus.</p>
Ondansetron Baxter	4 mg/2 mL injection	Recall	<p>Baxter announced a consumer-level recall of certain lots of ondansetron injection because the pH level parameter may be out of specification.</p> <p>Ondansetron is indicated for the prevention of nausea and vomiting associated with initial and repeat course of emetogenic cancer chemotherapy and for the prevention of postoperative nausea and/or vomiting.</p>
Over-the-counter eye drops Cardinal Health and Harvard Drug Group	Various formulations	Recall	<p>Cardinal Health, Harvard Drug Group, and Kilitch Healthcare India Limited announced a consumer level recall of all lots of over-the-counter (OTC) ophthalmic products supplied by Velocity Pharma. Both companies received information from the FDA indicating investigators found insanitary conditions in the manufacturing facility and positive bacterial test results from an environmental sampling of critical drug production areas in the facility.</p> <p>These OTC eye drops are used for temporary relief of burning and irritation due to dryness of the eye, for use as a protectant against further irritation or to relieve dryness of the eye, and/or to relieve redness of the eye due to minor eye irritations.</p>

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Sandimmune® (cyclosporine) Novartis	100 mg/mL oral solution	Recall	<p>Novartis announced a consumer level recall of two lots of Sandimmune oral solution because of crystal formation observed in some bottles, which could potentially result in incorrect dosing. No other Sandimmune formulations are impacted.</p> <p>Sandimmune is indicated for the prophylaxis of organ rejection in kidney, liver, and heart allogeneic transplants.</p>
Ting® (miconazole nitrate) Insight Pharmaceuticals	2% spray powder	Recall	<p>Insight Pharmaceuticals announced a voluntary consumer-level recall two lots of Ting Athlete's Foot Spray Antifungal Spray Powder because samples from these lots contained elevated levels of benzene related to the propellant that sprays the product out of the can. Benzene is not an ingredient in any Ting products.</p> <p>Miconazole is used to treat most athlete's foot, jock itch and ringworm. It is also used to relieve itching, scaling, burning and discomfort that can accompany athlete's foot and jock itch.</p>
VariSoft Infusion Set Unomedical A/S	Model #s 1002827, 1002828, 1002830	Recall	<p>Unomedical A/S announced a voluntary consumer-level recall of certain VariSoft Infusion Sets because there is a risk the connector may detach from the infusion set which will disrupt insulin delivery. If this occurs, insulin may continue to flow through the tubing that is now disconnected from the patient and the insulin pump would not recognize an infusion set problem and would not alert users.</p> <p>VariSoft is an infusion set used with Tandem™ insulin pumps for the subcutaneous infusion of insulin in the treatment of diabetes.</p>

Key guideline/Literature updates

Topic	Reference
American College of Cardiology and American Heart Association - Diagnosis and Management of Atrial Fibrillation	<u>Journal of the American College of Cardiology</u> . November 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Biliary Tract Cancers - Version 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Biliary Tract Cancers</u> . November 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer - Version 4.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer</u> . November 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Dermatofibrosarcoma Protuberans - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Dermatofibrosarcoma Protuberans</u> . November 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kaposi Sarcoma - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Kaposi Sarcoma</u> . November 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Merkel Cell Carcinoma - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Merkel Cell Carcinoma</u> . November 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Mesothelioma: Peritoneal - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Mesothelioma: Peritoneal</u> . November 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Mesothelioma: Pleural - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Mesothelioma: Pleural</u> . November 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes - Version 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes</u> . November 2023

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer - Version 5.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</u> November 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer - Version 6.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer.</u> November 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer - Version 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer.</u> November 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Squamous Cell Skin Cancer - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Squamous Cell Skin Cancer.</u> November 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thymomas and Thymic Carcinomas - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Thymomas and Thymic Carcinomas.</u> November 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer in People with HIV - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Cancer in People with HIV.</u> November 2023



At Optum, we help create a healthier world, one insight, one connection, one person at a time. All Optum trademarks and logos are owned by Optum, Inc., in the U.S. and other jurisdictions. All other trademarks are the property of their respective owners. This document contains information that is considered proprietary to Optum Rx and should not be reproduced without the express written consent of Optum Rx. RxHighlights® is published by the Optum Rx Clinical Services Department. © 2022 Optum, Inc. All rights reserved. ORX6547968C-TEMPLATE_220208