

RxHighlights

October 2023

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New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Agamree [®] (vamorolone) [†] Catalyst Pharmaceuticals	Dissociative steroidal anti-inflammatory drug	Treatment of Duchenne muscular dystrophy in patients 2 years of age and older	First Quarter of 2024
Bimzelx [®] (bimekizumab-bkzx) [*] UCB	Interleukin-17 receptor inhibitor	Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy	October 25, 2023
Cabtreo [™] (clindamycin phosphate/adapalene/benzoyl peroxide) Bausch Health	Retinoid/ antibiotic	Topical treatment of acne vulgaris in adult and pediatric patients 12 years of age and older	First Quarter of 2024
Combogesic [®] IV (acetaminophen/ibuprofen) Hyloris Pharmaceuticals	Non-salicylate analgesic/ NSAID	In adults where an intravenous route of administration is considered clinically necessary for the relief of mild to moderate pain or the management of moderate to severe pain as an adjunct to opioid analgesics	Early 2024
Cosentyx [®] (secukinumab) solution for IV injection Novartis	Interleukin-17A antagonist	Treatment of adults with active psoriatic arthritis, active ankylosing spondylitis, and active non-radiographic axial spondyloarthritis with objective signs of inflammation	October 11, 2023
Coxanto (oxaprozin) Solubiomix	NSAID	For relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis, and juvenile rheumatoid arthritis	TBD
Loqtorzi [™] (toripalimab-tpzi) ^{†*} Coherus and Junshi Biosciences	Anti-PD-1 monoclonal antibody	In combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or with recurrent, locally advanced	First Quarter of 2024

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
		nasopharyngeal carcinoma; as a single agent, for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy	
OmvoH™ (mirikizumab-mrkz)* Eli Lilly	Interleukin-23 antagonist	Treatment of moderately to severely active ulcerative colitis in adults	November 1, 2023
Penbraya™ (meningococcal groups A, B, C, W, and Y vaccine) Pfizer	Vaccine	Active immunization to prevent invasive disease caused by <i>Neisseria meningitidis</i> serogroups A, B, C, W, and Y	TBD
Qlosi™ (pilocarpine) Orasis Pharmaceuticals	Cholinergic muscarinic receptor agonist	Treatment of presbyopia in adults	First Half of 2024
Velsipity™ (etrasimod)* Pfizer	S1P1 receptor agonist	Treatment of moderately to severely active ulcerative colitis in adults	October 25, 2023
Xphozah® (tenapanor) Ardelyx	Sodium/hydrogen exchanger 3 inhibitor	To reduce serum phosphorus in adults with chronic kidney disease on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy	November 6, 2023
Zilbrysq® (zilucoplan)† UCB	Complement inhibitor	Treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor antibody positive	TBD
Zituvio™ (sitagliptin) Zydus Lifesciences	Dipeptidyl peptidase-4 inhibitor	An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	TBD
Zymfentra™ (infliximab-dyyb) Celltrion	Tumor necrosis factor blocker	In adults for maintenance treatment of moderately to severely active ulcerative colitis following treatment with an infliximab product administered intravenously (IV); moderately to severely active Crohn's disease following treatment with an infliximab product administered IV	TBD

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

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New biosimilars

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Wezlana™ (ustekinumab-auub)* Amgen	Dermatologicals	Patients 6 years and older with moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy; patients 6 years and older with active psoriatic arthritis; adult patients with moderately to severely active Crohn's disease, and adult patients with moderately to severely active ulcerative colitis	TBD

*interchangeable; TBD: To be determined

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New generics

Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Mydayis® (mixed-salts of a single-entity amphetamine product) Takeda	Teva†, SpecGX†, Sun†	12.5 mg, 25 mg, 37.5 mg, and 50 mg extended-release capsules	Treatment of attention deficit hyperactivity disorder in patients 13 years and older	October 10, 2023 [^]
Onexton® (clindamycin/benzoyl peroxide) Bausch Health	Taro†	1.2%/3.75% gel	Topical treatment of acne vulgaris in patients 12 years of age and older	October 2, 2023
Votrient® (pazopanib) Novartis	Sun†, Teva†	200 mg tablets	Treatment of adults with advanced renal cell carcinoma and advanced soft tissue sarcoma who have received prior chemotherapy	October 20, 2023

†A-rated generic manufacturer

[^] SpecGX and Sun received FDA approval of AB-rated generic versions of Mydayis on August 31, 2023 and September 27, 2023, respectively. Launch plans are pending

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New authorized brand alternatives

Drug name manufacturer(s)	Authorized brand alternative manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Onexton® (clindamycin/benzoyl peroxide) Bausch Health	Bausch Health, Oceanside	1.2%/3.75% gel	Topical treatment of acne vulgaris in patients 12 years of age and older	October 2, 2023

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Indications/Label updates

Drug name manufacturer(s)	Type	Description
Braftovi® (encorafenib) plus Mektovi® (binimetinib) Pfizer	New indication	Treatment of adult patients with metastatic non-small cell lung cancer with a BRAF V600E mutation, as detected by an FDA-approved test
Cosentyx® (secukinumab) Novartis	New indication	Treatment of adult patients with moderate to severe hidradenitis suppurativa
COVID-19 vaccine, adjuvanted (2023-2024 formula) Novavax	Emergency Use Authorization (EUA)	The FDA granted EUA for Novavax's Novavax COVID-19 vaccine, adjuvanted (2023-2024 formula), for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older
Enbrel® (etanercept) Amgen	New indication	Treatment of active juvenile psoriatic arthritis in pediatric patients 2 years of age and older
Keytruda® (pembrolizumab) Merck	Expanded indication	Treatment of patients with resectable (tumors \geq 4 cm or node positive) non-small cell lung cancer in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery
Opdivo® (nivolumab) Bristol Myers Squibb	Expanded indication	Adjuvant treatment of adult and pediatric patients 12 years and older with completely resected Stage IIB, Stage IIC, Stage III, or Stage IV melanoma

Drug name manufacturer(s)	Type	Description
Orencia [®] (abatacept) Bristol Myers Squibb	Expanded indication	Treatment of patients 2 years of age and older with active psoriatic arthritis
Rozlytrek [®] (entrectinib) 50 mg pellet per packet Genentech	Expanded indication, new formulation approval	Treatment of adult and pediatric patients older than 1 month of age with solid tumors that have a neurotrophic tyrosine receptor kinase gene fusion, as detected by an FDA-approved test without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy
Tibsovo [®] (ivosidenib) Servier	New indication	Treatment of adult patients with relapsed or refractory myelodysplastic syndromes with a susceptible isocitrate dehydrogenase-1 mutation as detected by an FDA-approved test
Vabysmo [®] (faricimab-svoa) Genentech	New indication	Treatment of patients with macular edema following retinal vein occlusion
Veltassa [®] (patiromer) single-use packets containing 1 gram Vifor Pharma	Expanded indication, new strength	Treatment of hyperkalemia in adults and pediatric patients ages 12 years and older
Voxzogo [®] (vosoritide) BioMarin	Expanded indication	To increase linear growth in pediatric patients with achondroplasia with open epiphyses
Zoryve [®] (roflumilast) Arcutis Biotherapeutics	Expanded indication	Topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older

[Learn more](#)**Drug safety news / Drug updates**

Drug name manufacturer(s)	Description
Cisplatin Fresenius Kabi	Cisplatin has been a shortage since February 2023 due to increased demand. To bolster supply, the FDA is providing Fresenius Kabi with special authorization to temporarily import their cisplatin product, Kemoplat, into the U.S. This product is not a FDA-approved product but is being given special authorization due to the shortage.
Cyltezo® (adalimumab-adbm) and unbranded adalimumab-adbm Sandoz, Boehringer Ingelheim, and Amgen	OptumRx announced beginning July 1, 2023 that its standard formulary would include three biosimilars at parity to Humira. Boehringer Ingelheim announced the launch of adalimumab-adbm, its low list biosimilar to Humira, also interchangeable

[Learn more](#)**Drug recalls/Withdrawals/Shortages/Discontinuations**

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Beyfortus™ (nirsevimab-alip) Sanofi	50 mg/0,5 mL and a 100 mg/1 mL single dose pre-filled syringe	Shortage	<p>There is a nationwide shortage of Sanofi's Beyfortus , a monoclonal antibody used in newborns and infants to protect against respiratory syncytial virus (RSV) disease due to increased demand.</p> <p>Beyfortus is on allocation with supply being distributed based on historical orders. Sanofi is working with their manufacturing partner, AstraZeneca, to accelerate additional supply and explore a number of actions to extend the manufacturing network.</p>
Exkivity® (mobocertinib) Takeda	40 mg capsules	Withdrawal	<p>Takeda announced the voluntary withdrawal of Exkivity. Exkivity was granted FDA approval under the accelerated approval pathway. It was approved for the treatment of non-small cell lung cancer with epidermal growth factor receptor exon 20 insertion mutations.</p> <p>A confirmatory phase 3 study did not meet its primary endpoint and thus did not fulfill the confirmatory data requirements of the accelerated approval granted.</p>

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
<p>Over-the-counter (OTC) eye drops Cardinal Health and Harvard Drug Group</p>	<p>Various OTC ophthalmic products</p>	<p>Recall</p>	<p>Cardinal Health and Harvard Drug Group announced a consumer level recall of all lots of 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>
<p>Sodium bicarbonate, midazolam, and ELCYS (cysteine hydrochloride) injection products Exela Pharma Sciences</p>	<p>Sodium bicarbonate 8.4% injection Midazolam in 0.8% sodium chloride injection ELCYS (cysteine hydrochloride) 500 mg/10 mL injection</p>	<p>Recall</p>	<p>Exela Pharma Sciences announced a consumer-level recall of several lots of sodium bicarbonate injection, one lot of midazolam in sodium chloride injection and one lot of ELCYS (cysteine hydrochloride) injection because of particulate matter identified as silicone.</p> <p>Sodium bicarbonate injection, is used for the treatment of metabolic acidosis.</p> <p>Midazolam in sodium chloride injection is used for sedation.</p> <p>ELCYS injection is used for nutritional requirements per total parenteral nutrition.</p>
<p>Sodium injection and lidocaine injection Hospira</p>	<p>Sodium bicarbonate 4.2% injection Lidocaine hydrochloride 1% and 2% injection</p>	<p>Recall</p>	<p>Hospira announced a user-level recall of one lot of sodium bicarbonate injection and two lots of lidocaine hydrochloride injection products because of the potential for presence of glass particulate matter.</p> <p>Sodium bicarbonate injection, is indicated in the treatment of metabolic acidosis, treatment of certain drug intoxications, and severe diarrhea .</p> <p>Lidocaine hydrochloride injection is indicated in the acute management of ventricular arrhythmias such as those occurring in relation to acute myocardial infarction, or during cardiac manipulation, such as cardiac surgery.</p>

Key guideline/Literature updates

Topic	Reference
National Institutes of Health – COVID-19 Treatment	<u>COVID-19 Treatment Guidelines</u> , November 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia - Version 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia</u> . October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia - Version 6.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia</u> . October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas - Version 6.2023	<u>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas</u> . October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma</u> . October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia</u> . October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia</u> . October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Head and Neck Cancers - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers</u> . October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma</u> . October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous - Version 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous</u> .

Topic	Reference
	October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma - Version 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma.</u> October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes - Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes.</u> October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms - Version 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms.</u> October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer - Version 4.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</u> October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia - Version 3.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia.</u> October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Penile Cancer - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Penile Cancer.</u> October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Systemic Light Chain Amyloidosis - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Systemic Light Chain Amyloidosis.</u> October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Vulvar Cancer - Version 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Vulvar Cancer.</u> October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer Risk Reduction - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Risk Reduction.</u> October 2023

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis - Version 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis.</u> October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal - Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal.</u> October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Lung Cancer Screening - Version 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Lung Cancer Screening.</u> October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue - Version 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue.</u> October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Distress Management - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Distress Management.</u> October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation - Version 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation.</u> October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors.</u> October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities - Version 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities.</u> October 2023



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