

RxHighlights

March 2024

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New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Clobetasol propionate ophthalmic suspension Formosa Pharmaceuticals, AimMax Therapeutics	Corticosteroid	Treatment of post-operative inflammation and pain following ocular surgery	Middle of 2024
Duvyzat™ (givinostat)†* Italfarmaco	Histone deacetylase inhibitor	Treatment of Duchenne muscular dystrophy in patients 6 years of age and older	TBD
Lenmeldy™ (atidarsagene autotemcel)†* Orchard Therapeutics	Gene therapy	Treatment of children with pre-symptomatic late infantile, presymptomatic early juvenile or early symptomatic early juvenile metachromatic leukodystrophy	March 22, 2024
Letybo (letibotulinumtoxinA-wlbg) Hugel	Botulinum toxins	Temporary improvement in the appearance of moderate to severe glabellar (frown) lines associated with corrugator and/or procerus muscle activity in adult patients	Second half of 2024
Opsynvi® (macitentan/tadalafil)† Johnson & Johnson	Endothelin receptor antagonist/ phosphodiesterase 5 inhibitor	Chronic treatment of adults with pulmonary arterial hypertension (PAH, WHO Group I and WHO Functional Class [FC] II-III).	April 2, 2024
Rezdiffra™ (resmetirom)* Madrigal Pharmaceuticals	Beta-selective thyroid hormone receptor agonist	In conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).	March 18, 2024

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Tevimbra [®] (tislelizumab-jsgr) ^{†*} BeiGene	Programmed death-1 inhibitor	A single agent, for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor	Second half of 2024
Tryvio [™] (aprocitentan)* Idorsia	Endothelin receptor antagonist	In combination with other antihypertensive drugs, for the treatment of hypertension, to lower blood pressure in adult patients who are not adequately controlled on other drugs	Second half of 2024
Vafseo [®] (vadadustat)* Akebia	Hypoxia-inducible factor-prolyl hydroxylase inhibitor	Treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least three months	January 2025
Winrevair [™] (sotatercept) ^{†*} Merck	Activin receptor type IIA-Fc fusion protein	Treatment of adults with pulmonary arterial hypertension (PAH, World Health Organization [WHO] Group 1) to increase exercise capacity, improve WHO functional class, and reduce the risk of clinical worsening events	April 3, 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
<p>Jubbonti[®] (denosumab-bbdz)[§] Sandoz</p>	<p>Nuclear factor kappa-B (RANK) ligand receptor activator</p>	<p>Treatment of postmenopausal women with osteoporosis at high risk for fracture; treatment to increase bone mass in men with osteoporosis at high risk for fracture; treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture; treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer; and treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer</p>	<p>TBD</p>
<p>Tyenne[®] (tocilizumab-aazg) Fresenius Kabi</p>	<p>Anti-interleukin-6 (anti-IL-6) receptor monoclonal antibody (MAb)</p>	<p>Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs; treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older; treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older; and treatment of giant cell arteritis</p>	<p>TBD</p>
<p>Wyost[®] (denosumab-bbdz)[*] Sandoz</p>	<p>Nuclear factor kappa-B (RANK) ligand receptor activator</p>	<p>Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors; treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity; and treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy</p>	<p>TBD</p>

^{*}interchangeable with Xgeva (denosumab); [§]interchangeable with Prolia (denosumab); 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
Thiola EC[®] (tiopronin) Mission Pharmacal	Amneal [†] , Torrent [†]	100 mg and 300 mg delayed-release tablets	Prevention of cystine stone formation in patients with severe homozygous cystinuria	February 27, 2024 [^]

[†]A-rated generic manufacturer
[^]Torrent launch date; Amneal launch date pending

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Indications/Label updates

Drug name manufacturer(s)	Type	Description
Besponsa[™] (inotuzumab ozogamicin) Pfizer	Updated indication	Treatment of relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia in adult and pediatric patients 1 year and older
Breyanzi[®] (lisocabtagene maraleucel) Bristol Myers Squibb	New indication	Treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma who have received at least 2 prior lines of therapy including, a Bruton tyrosine kinase inhibitor and a B-cell lymphoma 2 inhibitor
Brukinsa[®] (zanubrutinib) BeiGene	New indication	Treatment of adult patients with relapsed or refractory follicular lymphoma, in combination with obinutuzumab, after two or more lines of systemic therapy
Edurant[®] (rilpivirine) Janssen	Expanded indication; new formulation	In combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV)-1 infection in treatment-naïve patients 2 years of age and older and weighing at least 14 kg with HIV-1 RNA less than or equal to 100,000 copies/mL To support the expanded indication, Edurant PED 2.5 mg tablet for oral suspension was also approved
Iclusig[®] (ponatinib) Takeda	Expanded indication	In combination with chemotherapy, for treatment of adult patients with newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia

Drug name manufacturer(s)	Type	Description
Ixinity [®] (coagulation factor IX [recombinant]) Medexus Pharma	Expanded indication	In adults and children with hemophilia B for on-demand treatment and control of bleeding episodes; perioperative management; and routine prophylaxis to reduce the frequency of bleeding episodes
Livmarli [®] (maralixibat) Mirum Pharmaceuticals	New indication	Treatment of cholestatic pruritus in patients 5 years of age and older with progressive familial intrahepatic cholestasis
Nexleto [®] (bempedoic acid); Nexlizet [®] (bempedoic acid/ezetimibe) Esperion	New/expanded indications	To reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with: (1) established cardiovascular disease (CVD), or (2) a high risk for a CVD event but without established CVD. Other indication was also expanded to adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia.
Opdivo [®] (nivolumab) Bristol Myers Squibb	New indication	First-line treatment of adult patients with unresectable or metastatic urothelial carcinoma
Pemgarda [™] (pemivibart) Invivyd	Emergency use authorization approval (EUA)	Preexposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and adolescents (12 years of age and older weighing at least 40 kg): who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2; and who have moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and are unlikely to mount an adequate response to COVID-19 vaccination
Praluent [®] (alirocumab) Regeneron	Expanded indication	Adjunct to diet and other low density lipoprotein cholesterol (LDL-C)-lowering therapies in pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia to reduce LDL-C
Spevigo [®] (spesolimab-sbzo) Boehringer Ingelheim	Expanded indication	Treatment of generalized pustular psoriasis in adults and pediatric patients 12 years of age and older and weighing at least 40 kg
Rybrevant [®] (amivantamab-vmjw) Johnson & Johnson	New indication; accelerated approval converted to full approval	In combination with carboplatin and pemetrexed, for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor exon 20 insertion mutations, as detected by an FDA-approved test

Drug name manufacturer(s)	Type	Description
Ultomiris® (ravulizumab-cwvz) AstraZeneca	New indication	Treatment of adult patients with neuromyelitis optica spectrum disorder who are anti-aquaporin-4 antibody positive
Vemlidy® (tenofovir alafenamide) Gilead	New indication	Treatment of chronic hepatitis B virus infection in adults and pediatric patients 6 years of age and older and weighing at least 25 kg with compensated liver disease
Wegovy® (semaglutide) Novo Nordisk	New indication	In combination with a reduced calorie diet and increased physical activity, to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight
Xhance® (fluticasone propionate) OptiNose	New indication	Treatment of chronic rhinosinusitis without nasal polyps in adults.
Xofluza® (baloxavir marboxil) Genentech	Expanded indication	Treatment of acute uncomplicated influenza in patients 5 years of age and older who have been symptomatic for no more than 48 hours and who are otherwise healthy or at high risk of developing influenza-related complications

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Drug recalls/Withdrawals/Shortages/Discontinuations

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Methocarbamol Eugia	1000 mg/10 mL (100 mg/mL), single dose vial for injection	Recall	Eugia announced a consumer-level recall of one lot of methocarbamol injection because of a customer complaint for the presence of white particles floating inside the vial. Methocarbamol injection is used as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions.

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Potassium chloride B. Braun Medical	2 meq/mL injection	Recall	<p>B. Braun Medical announced a consumer-level recall of two lots of potassium chloride for injection due to potential for fluid leakage.</p> <p>Potassium chloride for injection is indicated in the treatment of potassium deficiency states when oral replacement is not feasible.</p>
Treprostinil Par	20 mg/20 mL injection	Recall	<p>Par announced a consumer-level recall of one lot of treprostinil injection due to the potential for the presence of silicone particulates in the product solution.</p> <p>Treprostinil is indicated for the treatment of pulmonary arterial hypertension (PAH) to diminish symptoms associated with exercise and in patients requiring transition from epoprostenol.</p>
Vancomycin Amneal	250 mg/5mL oral solution	Recall	<p>Amneal announced a consumer-level recall of four lots of vancomycin oral solution because some bottles may have been overfilled which can result in a super potent dosing regimen.</p> <p>Vancomycin oral solution is used for the treatment of enterocolitis caused by <i>Staphylococcus aureus</i> (including methicillin-resistant strains) and antibiotic-associated pseudomembranous colitis caused by <i>C. difficile</i>.</p>

Key guideline/Literature updates

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia Version - 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer Version - 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bone Cancer Version - 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Bone Cancer.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer Version - 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Version - 3.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers Version - 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastric Cancer Version - 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastrointestinal Stromal Tumors Version - 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Gastrointestinal Stromal Tumors.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Histiocytic Neoplasms Version - 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Histiocytic Neoplasms.</u> March 2024

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma Version - 3.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kidney Cancer Version - 3.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous Version - 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma Version - 3.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer Version - 3.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia Version - 5.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer Version - 3.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Systemic Mastocytosis Version - 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Systemic Mastocytosis.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: T-Cell Lymphomas Version - 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Testicular Cancer Version - 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Testicular Cancer.</u> March 2024

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thyroid Carcinoma Version - 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Uterine Neoplasms Version - 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Vaginal Cancer Version - 1.2025	<u>NCCN Clinical Practice Guidelines in Oncology: Vaginal Cancer.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer Risk Reduction Version - 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Risk Reduction.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis Version - 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection Version - 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adult Cancer Pain Version - 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Distress Management Version - 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Distress Management.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Survivorship Version - 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Survivorship.</u> March 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer in People with HIV Version - 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Cancer in People with HIV.</u> March 2024



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