

RxHighlights

June 2024

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New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Capvaxive™ (pneumococcal 21-valent conjugate vaccine) Merck	Vaccine	Active immunization for the prevention of invasive disease caused by <i>Streptococcus pneumoniae</i> serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older Active immunization for the prevention of pneumonia caused by <i>S. pneumoniae</i> serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older	June 17, 2024
Chewtadzy (tadalafil) ANI Pharmaceuticals	Phosphodiesterase 5 inhibitor	Treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in adult males; and treatment of erectile dysfunction and the signs and symptoms of BPH in adult males	TBD
Iqirvo® (elafibranor) ^{†*} Ipsen	Selective peroxisome proliferator-activated receptor modulator	Treatment of primary biliary cholangitis in combination with ursodeoxycholic acid in adults who have had an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA	June 13, 2024
Ohtuvayre™ (ensifentrine) [*] Verona Pharma	Phosphodiesterase-3 and phosphodiesterase-4 inhibitor	Maintenance treatment of chronic obstructive pulmonary disease in adult patients	July 1, 2024
Piasky (crovalimab-akkz) [†] Genentech	C5 inhibitor	Treatment of adult and pediatric patients 13 years and older with paroxysmal nocturnal hemoglobinuria (PNH) and body weight of at least 40 kg	TBD
Rytelo™ (imetelstat) ^{†*}	Telomerase inhibitor	Treatment of adult patients with low-to intermediate-1 risk myelodysplastic syndromes with transfusion-dependent anemia	June 27, 2024

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Geron		requiring 4 or more red blood cell units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents	
Sofdra™ (sofipironium) Botanix	Anticholinergic	Treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older	July 1, 2024
Vigafyde™ (vigabatrin) [†] Pyros Pharmaceuticals	Anticonvulsant	As monotherapy for the treatment of infantile spasms in pediatric patients 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss	TBD
Yimmugo® (immune globulin intravenous, human - dira) Grifols	Immune globulin	Treatment of primary humoral immunodeficiency including but not limited to the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies in patients 2 years of age and older	TBD

*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>Nypozi™ (filgrastim-txid) Tanvex</p>	<p>Granulocyte-colony stimulating factor</p>	<p>Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever</p> <p>Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia</p> <p>Reduce the duration of neutropenia and neutropenia-related clinical sequelae in patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation</p> <p>Reduce the incidence and duration of sequelae of severe neutropenia in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia</p> <p>Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis</p> <p>Increase survival in patients acutely exposed to myelosuppressive doses of radiation.</p>	<p>TBD</p>

TBD: To be determined

New generics

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Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
<p>Somatuline® Depot (lanreotide) Ipsen</p>	<p>Cipla[†]</p>	<p>120 mg/0.5 mL, 60 mg/0.2 mL and 90 mg/0.3 mL injection</p>	<p>Acromegaly; Gastroenteropancreatic neuroendocrine tumors; Carcinoid syndrome</p>	<p>May 23, 2024[^]</p>

[†]AB-rated generic version

[^]Launch for 120 mg/0.5 mL; 60 mg/0.2 mL and 90 mg/0.3 mL launch TBD

New authorized brand alternatives

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Drug name manufacturer(s)	Authorized brand alternative manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Victoza® (liraglutide) Novo Nordisk	Teva	18 mg/3 mL (6 mg/mL) injection	Adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus To reduce the risk of major adverse cardiovascular (CV) events in adults with T2DM and established CV disease	June 24, 2024

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Indications/Label updates

Drug name manufacturer(s)	Type	Description
Arexvy® (respiratory syncytial virus vaccine) GSK	Expanded indication	Prevention of lower respiratory tract disease caused by respiratory syncytial virus in individuals 50 through 59 years of age who are at increased risk for LRTD caused by RSV.
Augtyro™ (repotrectinib) Bristol Myers Squibb	New Indication	Treatment of adult and pediatric patients 12 years of age and older with solid tumors that: have a neurotrophic tyrosine receptor kinase gene fusion, are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy
Blincyto® (blinatumomab) Amgen	New Indication	Treatment of CD19-positive Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia in the consolidation phase of multiphase chemotherapy in adult and pediatric patients one month and older
Elevidys®	Accelerated approval converted	Treatment of Duchenne muscular dystrophy in individuals at least 4 years of age who are ambulatory and have a confirmed mutation in the DMD gene

Drug name manufacturer(s)	Type	Description
(delandistrogene moxeparvovec-rokl) Sarepta	to traditional approval	
	Expanded indication	Treatment of DMD in individuals at least 4 years of age who are non-ambulatory and have a confirmed mutation in the DMD gene
Epkinly [®] (epcoritamab-bysp) AbbVie, Genmab	New indication	Treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy
Farxiga [®] (dapagliflozin), Xigduo [®] XR (dapagliflozin/metformin)	Expanded indication	Adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus
Imfinzi [®] (durvalumab) AstraZeneca	New indication	In combination with carboplatin and paclitaxel followed by Imfinzi as a single agent for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient
Kevzara [®] (sarilumab) Regeneron and Sanofi	New indication	Treatment of active polyarticular juvenile idiopathic arthritis in patients who weigh 63 kg or greater
Krazati [®] (adagrasib) Bristol Myers Squibb	New indication	Treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic colorectal cancer, as determined by an FDA-approved test, who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy
Keytruda [®] (pembrolizumab) Merck	New indication	In combination with carboplatin and paclitaxel, followed by Keytruda as a single agent for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma
Motpoly XR [™] (lacosamide) Aucta Pharmaceuticals'	New Indication	Treatment of primary generalized tonic-clonic seizures in adults and in pediatric patients weighing at least 50 kg
Skyrizi [®] (risankizumab-rzaa) AbbVie	New indication	Treatment of moderately to severely active ulcerative colitis in adults
Vyvgart [®] Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) Argenx	New indication	Treatment of adult patients with generalized myasthenia gravis who are anti-acetylcholine receptor antibody positive

Drug name manufacturer(s)	Type	Description
<p>Wakix® (pitolisant) Harmony Biosciences</p>	<p>Expanded indication</p>	<p>Treatment of excessive daytime sleepiness in pediatric patients 6 years of age and older with narcolepsy Treatment of EDS or cataplexy in adult patients with narcolepsy</p>

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Drug safety news / Drug updates

Drug name manufacturer(s)	Description
<p>COVID-19 vaccines</p>	<p>The FDA’s Vaccine and Related Biological Products Advisory Committee unanimously voted for the 2024 - 2025 formula of COVID-19 vaccines in the U.S. to include a monovalent JN.1-lineage. The FDA advised that the preferred JN.1-lineage for the COVID-19 vaccines (2024 - 2025 formula) is the KP.2 strain., if feasible. Advisory Committee on Immunization Practice unanimously voted for 2024 – 2025 COVID-19 vaccines as authorized or approved by the FDA in persons ≥ 6 months of age.</p>
<p>Tirzepatide Eli Lilly</p>	<p>Eli Lilly presented the positive results from the SURMOUNT-OSA Phase 3 trials for tirzepatide for the treatment of moderate-to-severe obstructive sleep apnea in adults with obesity at the American Diabetes Association 84th Scientific Sessions</p>
<p>Respiratory syncytial virus vaccines</p>	<p>The CDC updated its recommendations for the use of respiratory syncytial virus (RSV) vaccines in people ages 60 years and older. For this upcoming RSV season, the CDC now recommends: Everyone ages 75 and older receive the RSV vaccine; and people ages 60 to 74 who are at increased risk of severe RSV, meaning they have certain chronic medical conditions, such as lung or heart disease, or they live in nursing homes, receive the RSV vaccine.</p>

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Drug recalls/Withdrawals/Shortages/Discontinuations

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Accu-Chek® Guide Kit Roche	n/a	Recall	Roche announced a user-level recall of some Accu-Chek Guide Kits because they were configured incorrectly and show results in mmol/L rather than in the labeled measuring unit, mg/dL. Accu-Chek Guide is a blood glucose meter used to measure blood sugar levels in people with diabetes.
Buprenorphine Hospira	0.3 mg base/mL injection	Recall	Hospira announced a voluntary user-level recall of two lots of buprenorphine injection due to the potential for incomplete crimp seals; one customer complaint has been received for one leaking unit. Buprenorphine injection is indicated for the management of pain requiring an opioid analgesic and for which alternate treatments are inadequate.
Labetalol Hospira	20 mg/4 mL injection	Recall	Hospira announced a voluntary user-level recall of three lots of labetalol injection due to the potential for incomplete crimp seals; one customer complaint has been received for one leaking unit. Labetalol injection is indicated for control of blood pressure in severe hypertension.
Docetaxel Sagent	160 mg/16 mL (10 mg/mL) and 80 mg/8 mL (10 mg/mL) injection	Recall	Sagent announced a user-level recall of two lots of docetaxel injection because of a customer complaint due to potential presence of particulate matter from the stopper in the drug product. Docetaxel is indicated for the treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, and head and neck cancer.
Potassium chloride Glenmark	(750 mg) 10 mEq K extended-release capsules	Recall	Glenmark announced a consumer level recall of 114 lots of potassium chloride extended-release capsules because they may not dissolve as intended. Potassium chloride extended-release capsules are used for the treatment of patients with low potassium.

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Potassium chloride American Health Packaging	(750 mg) 10 mEq K extended-release capsules	Recall	American Health Packaging announced a consumer level recall of 21 lots of potassium chloride extended-release capsules because they may not dissolve as intended. Potassium chloride extended-release capsules are used for the treatment of patients with low potassium .

Key guideline/Literature updates

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia</u> . June 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Biliary Tract Cancers - Version 3.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Biliary Tract Cancers</u> . June 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer - Version 4.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer</u> . June 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer - Version 4.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer</u> . June 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatocellular Carcinoma - Version 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Hepatocellular Carcinoma</u> . June 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kidney Cancer - Version 1.2025	<u>NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer</u> . June 2024

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions - Version 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions .</u> June 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Neuroblastoma - Version 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Neuroblastoma.</u> June 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors.</u> June 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer - Version 7.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer .</u> June 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer - Version 3.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer .</u> June 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma - Version 4.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma .</u> June 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer - Version 3.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer .</u> June 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thyroid Carcinoma - Version 3.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma .</u> June 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer - Version 3.2024 (Sub-Saharan Africa)	<u>NCCN Harmonized Guidelines: Breast Cancer</u> June 2024



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