

RxHighlights

April 2024

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New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Anktiva [®] (nogapendekin alfa inbakicept-pmIn) [*] ImmunityBio	Interleukin-15 receptor agonist	Treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer with carcinoma in situ with or without papillary tumors	April 29, 2024
Beqvez [™] (fidanacogene elaparvovec-dzkt) [†] Pfizer	Gene therapy	Treatment of adults with moderate to severe hemophilia B (congenital factor IX deficiency) who currently use factor IX prophylaxis therapy, or have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes, and, do not have neutralizing antibodies to adeno-associated virus serotype Rh74var capsid as detected by an FDA-approved test	TBD
Entresto [®] Sprinkle (sacubitril/valsartan) Novartis	Neprilisin inhibitor/angiotensin II receptor blocker	To reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure and for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older	TBD
Ingrezza [®] Sprinkle (valbenazine) [†] Neurocrine Biosciences	Vesicular monoamine transporter 2 inhibitor	Treatment of adults with tardive dyskinesia or chorea associated with Huntington’s disease	TBD
Libervant [™] (diazepam) [†] Aquestive Therapeutics	Benzodiazepine	Acute treatment of intermittent, stereotypic episodes of frequent seizure activity (ie, seizure clusters, acute repetitive seizures) that are distinct from a patient’s usual seizure pattern in patients with epilepsy 2 to 5 years of age	May 01, 2024
Ojemda [™] (tovorafenib) ^{††} Day One Pharmaceuticals	Kinase inhibitor	Treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma harboring a BRAF fusion or rearrangement, or BRAF V600 mutation	April 26, 2024

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Pivya™ (pivmecillinam)* Utility Therapeutics	Penicillin class	Treatment of female patients 18 years of age and older with uncomplicated urinary tract infections caused by susceptible isolates of <i>Escherichia coli</i> , <i>Proteus mirabilis</i> , and <i>Staphylococcus saprophyticus</i>	TBD
Retevmo® (selpercatinib) tablet Eli Lilly	Kinase inhibitor	Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with a rearranged during transfection (RET) gene fusion, as detected by an FDA-approved test; adult and pediatric patients 12 years of age and older with advanced or metastatic medullary thyroid cancer with a RET mutation, as detected by an FDA-approved test, who require systemic therapy; adult and pediatric patients 12 years of age and older with advanced or metastatic thyroid cancer with a RET gene fusion, as detected by an FDA-approved test, who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate); and adult patients with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options	TBD
Rezenopy (naloxone) nasal spray Summit Biosciences	Opioid antagonist	Emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression in adult and pediatric patients	TBD
Risvan® (risperidone) Rovi	Atypical antipsychotic	Treatment of schizophrenia in adults	TBD
Vijoice® (alpelisib) oral granules Novartis	Kinase inhibitor	Treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum who require systemic therapy	TBD
Voydeya™ (danicopan)*† AstraZeneca	Complement factor D inhibitor	Add-on therapy to Ultomiris® (ravulizumab) or Soliris® (eculizumab) for the treatment of extravascular hemolysis in adults with paroxysmal nocturnal hemoglobinuria	April 4, 2024
Xolremdi™ (mavorixafor)*† X4 Pharmaceuticals	CXC receptor type 4 inhibitor	In patients 12 years of age and older with WHIM syndrome to increase the number of circulating mature neutrophils and lymphocytes	May 7, 2024

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Xromi (hydroxyurea) [†] Rare Disease Therapeutics	Antimetabolite	To reduce the frequency of painful crises and reduce the need for blood transfusions in pediatric patients aged 6 months of age to less than 2 years, with sickle cell anemia with recurrent moderate to severe painful crises	TBD
Zevtera (ceftobiprole medocartil sodium) [*] Basilea Pharmaceutica	Cephalosporin antibiotic	Treatment of adult patients with <i>Staphylococcus aureus</i> bloodstream infection (bacteremia), including those with right-sided infective endocarditis, caused by methicillin-susceptible and methicillin-resistant isolates; adult patients with acute bacterial skin and skin structure infections caused by susceptible isolates of the following gram-positive and gram-negative microorganisms: <i>Staphylococcus aureus</i> (methicillin-susceptible and methicillin-resistant isolates), <i>Streptococcus pyogenes</i> , and <i>Klebsiella pneumoniae</i> ; adult and pediatric patients (3 months to less than 18 years old) with community-acquired bacterial pneumonia caused by susceptible isolates of the following gram-positive and gram-negative microorganisms: <i>Staphylococcus aureus</i> (methicillin-susceptible isolates), <i>Streptococcus pneumoniae</i> , <i>Haemophilus influenzae</i> , <i>Haemophilus parainfluenzae</i> , <i>Escherichia coli</i> , and <i>Klebsiella pneumoniae</i>	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
Hercessi [™] (trastuzumab-strf) Accord BioPharma	Antineoplastics & Adjunctive Therapies	Adjuvant treatment of breast cancer, metastatic breast cancer, and metastatic gastric or gastroesophageal junction adenocarcinoma	TBD
Selarsdi [™] (ustekinumab-aekn) Alvotect, Teva	Dermatologicals	For adults and pediatric patients 6 years and older with moderate to severe plaque psoriasis, who are candidates for phototherapy or	TBD

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
		systemic therapy and adults and pediatric patients 6 years and older with active psoriatic arthritis	
Tyenne[®] (tocilizumab-aazg) Fresenius Kabi	Analgesic/Anti-Inflammatory/Migraine/Gout Agents/Anesthetics	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; giant cell arteritis; treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis and active systemic juvenile idiopathic arthritis.	4/15/2024*

*Launch applies to intravenous formulation; subcutaneous launch TBD
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
EstroGel[®] (estradiol) Ascent Therapeutics	Solaris ^{†±}	0.06% transdermal gel	Moderate to severe vasomotor symptoms due to menopause, and moderate to severe symptoms of vulvar and vaginal atrophy due to menopause	4/25/2024
Myrbetriq[®] (mirabegron) Astellas	Lupin [†] , Zydus [†]	25 mg extended-release tablets	Overactive bladder; neurogenic detrusor overactivity in pediatric patients	TBD

[†]AB-rated generic version manufacturer; [±]Granted 180-days of exclusivity
TBD: To be determined

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Indications/Label updates

Drug name manufacturer(s)	Type	Description
Abecma [®] (idecabtagene vicleucel) Bristol Myers Squibb, 2seventy Bio	Expanded indication	Treatment of adult patients with relapsed or refractory multiple myeloma after two or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody
Alecensa [®] (alectinib) Genentech	New Indication	Adjuvant treatment in adult patients following tumor resection of anaplastic lymphoma kinase-positive non-small cell lung cancer as detected by an FDA-approved test
Carvykti [®] (ciltacabtagene autoleucel) Johnson & Johnson	Expanded indication	Treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, and are refractory to lenalidomide
Dovato (dolutegravir/lamivudine) ViiV Healthcare	Expanded indication	As a complete regimen for treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 25 kg with no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of Dovato
Enhertu [®] (fam-trastuzumab deruxtecan-nxki) Daiichi Sankyo, AstraZeneca	New indication	Treatment of adult patients with unresectable or metastatic HER2-positive solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options
Entyvio [®] (vedolizumab) subcutaneous injection Takeda	New indication	Maintenance treatment in adults with moderately to severely active Crohn's disease after induction therapy with intravenous Entyvio
Fanapt [®] (iloperidone) Vanda Pharmaceuticals	New indication	Treatment of manic or mixed episodes associated with bipolar I disorder in adults
Fasenra [®] (benralizumab) AstraZeneca	Expanded indication	Treatment of patients aged 6 years and older with severe asthma, and with an eosinophilic phenotype
Lutathera [®] (lutetium Lu 177 dotatate)	Expanded indication	Treatment of adult and pediatric patients 12 years and older with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors

Drug name manufacturer(s)	Type	Description
Novartis		
Mircera ® (methoxy polyethylene glycol-epoetin beta) Vifor	Expanded indication	Treatment of anemia associated with chronic kidney disease in pediatric patients 3 months to 17 years of age on dialysis or not on dialysis who are converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA.
Otezla ® (apremilast) Amgen	Expanded indication	Treatment of pediatric patients 6 years of age and older and weighing at least 20 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
Rinvoq ® (upadacitinib), Rinvoq LQ (upadacitinib) Novartis	New/expanded indications; New formulation	<p>Treatment of adults and pediatric patients 2 years of age and older with active psoriatic arthritis who have had an inadequate response or intolerance to one or more tumor necrosis factor blockers.</p> <p>Treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis who have had an inadequate response or intolerance to one or more TNF blockers.</p> <p>To support the new/expanded indications, the FDA approved a 1 mg/mL oral solution formulation.</p>

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Drug recalls/Withdrawals/Shortages/Discontinuations

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Atovaquone Avkare	750 mg/5 mL oral suspension	Recall	<p>AvKARE announced a consumer level recall of one lot of atovaquone oral suspension because of potential <i>Bacillus cereus</i> contamination in the product found during stability testing at a 3rd party lab.</p> <p>Atovaquone is indicated for prevention and treatment of <i>Pneumocystis jiroveci</i> pneumonia in adults and children 13 years of age and older who cannot tolerate other medicines, such as trimethoprim-sulfamethoxazole.</p>

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Cloderm® (clocortolone pivalate) and Minolira™ (minocycline) EpiHealth	Cloderm: 0.1% cream Minolira: 105 mg and 135 mg ER tablets	Recall	<p>EpiHealth announced a voluntary consumer-level recall of some lots of Cloderm and Minolira as a result of the company declaring bankruptcy in July 2023.</p> <p>Cloderm is a topical steroid indicated for the relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.</p> <p>Minolira is indicated to treat the inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.</p>
Cyclophosphamide XGen Pharmaceuticals	500 mg, 1 gm injection	Recall	<p>XGen Pharmaceuticals announced a consumer level recall of two lots of cyclophosphamide injection because there was an error on the Physician's Insert, section 2.3, Preparation, Handling, and Administration.</p> <p>Cyclophosphamide is indicated for the treatment of malignant lymphomas, Hodgkins disease, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitts lymphoma, multiple myeloma, leukemias, mycosis fungoides, neuroblastoma, adenocarcinoma of the ovary, retinoblastoma, carcinoma of the breast, and treatment of biopsy proven minimal change nephrotic syndrome in pediatric patients.</p>
Relyvrio® (sodium phenylbutyrate/taurursodiol) Amylyx Pharmaceuticals	3g/1g per packet oral suspension	Discontinuation	<p>Amylyx Pharmaceuticals announced that it has started a process with the FDA to voluntarily discontinue the marketing authorization for Relyvrio and remove the product from the market based on topline results from the Phase 3 PHOENIX trial.</p> <p>Relyvrio is approved for the treatment of amyotrophic lateral sclerosis in adults.</p>
Sapropterin Dr Reddy's	100 mg powder for oral solution	Recall	<p>Dr. Reddy's announced a consumer-level recall of six lots of sapropterin powder for oral solution because of powder discoloration in some packets leading to decreased potency.</p> <p>Sapropterin is indicated to reduce blood phenylalanine levels in patients with hyperphenylalaninemia due to tetrahydrobiopterin responsive Phenylketonuria.</p>

Key guideline/Literature updates

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas - Version 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Biliary Tract Cancers - Version - 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Biliary Tract Cancers.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer - Version 3.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer Version - 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers - Version - 3.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia - Version 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Head and Neck Cancers Version - 4.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatocellular Carcinoma Version - 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Hepatocellular Carcinoma.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma Version - 4.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer Version - 5.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</u>

Topic	Reference
	April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Occult Primary Version - 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Occult Primary.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma Version - 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Aggressive Mature B-Cell Lymphomas Version - 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Aggressive Mature B-Cell Lymphomas.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer Version - 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma Version - 3.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma Version - 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Systemic Mastocytosis Version - 3.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Systemic Mastocytosis.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: T-T-Cell Lymphomas Version - 3.2024	<u>NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Vulvar Cancer Version - 4.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Vulvar Cancer.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis Version - 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis.</u>

Topic	Reference
	April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer-Associated Venous Thromboembolic Disease Version - 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Cancer-Associated Venous Thromboembolic Disease.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation Version - 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prevention and Treatment of Cancer-Related Infections Version - 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Prevention and Treatment of Cancer-Related Infections.</u> April 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Smoking Cessation Version - 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Smoking Cessation.</u> April 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> April 2024

