

RxHighlights

January 2023

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New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Airsupra™ (albuterol/budesonide) AstraZeneca	Glucocorticoid/short acting beta agonist	As-needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations in patients with asthma 18 years of age and older	TBD
Brenzavvy™ (bexagliflozin)* TheracosBio	Sodium glucose cotransporter 2 inhibitor	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	TBD
Jaypirca™ (pirtobrutinib)* Eli Lilly	Kinase inhibitor	Treatment of adult patients with relapsed or refractory mantle cell lymphoma after at least two lines of systemic therapy, including a Bruton's tyrosine kinase inhibitor	January 31, 2023
Leqembi™ (lecanemab-irmb)* Eisai, Biogen	Beta-amyloid monoclonal antibody	Treatment of Alzheimer's disease	January 11, 2023
Orserdu™ (elacestrant)* Menarini Group, Stemline Therapeutics	Selective estrogen receptor degrader	Treatment of postmenopausal women or adult men with estrogen receptor-positive, human epidermal growth factor receptor 2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy	February 1, 2023
Rykindo® (risperidone) 12.5 mg, 25 mg, 37.5 mg and 50 mg extended-release injectable suspension Luye Pharma	Atypical antipsychotic	Treatment of schizophrenia in adults and as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder in adults	TBD

*New molecular entity; 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
Cambia [®] (diclofenac potassium) Assertio Therapeutics	Par [†] , Alkem/Ascend [†] and Camber/Annora [†]	50 mg oral solution	Acute treatment of migraine	January 4, 2023
Esbriet [®] (pirfenidone) Genentech	Amneal [†] , Cipla [†] , Laurus [†] and Sandoz [†]	267 mg capsule	Idiopathic pulmonary fibrosis	January 10, 2023 [^]
Keveyis [®] (dichlorphenamide) Xeris	Torrent [†]	50 mg tablets	Primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants	January 27, 2023
Liptruzet [®] (atorvastatin/ezetimibe) [§] Merck	Althera	10 mg tablets	Primary hyperlipidemia and homozygous familial hypercholesterolemia.	January 4, 2023
Mirvaso [®] (brimonidine) Galderma	Padagis Israel [†]	0.33% topical gel	Persistent (nontransient) erythema of rosacea	January 4, 2023
Trokendi XR [®] (topiramate) Supernus	Zydus [†]	25 mg, 50 mg, and 100 mg extended-release capsules [¶]	Initial monotherapy for the treatment of partial-onset or primary generalized tonic- clonic seizures in patients 6 years of age and older; as adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 6 years of age and older; and for the preventive treatment of migraine in patients 12 years of age and older	January 4, 2023

[†]A-rated generic manufacturer

^{*}Received FDA-approval on December 20, 2022; Launch TBD

[^]Accord and ScieGen received FDA approval of AB-rated generic versions of Esbriet capsule on January 20, 2022 and August 1, 2022, respectively. Launch TBD.

[§]Brand Liptruzet was discontinued in 2015. [¶]The 200 mg XR strength is not generically available.

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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
Cambia [®] (diclofenac potassium) Assertio Therapeutics	Leading Pharma	50 mg oral solution	Acute treatment of migraine	January 3, 2023
Xyrem [®] (sodium oxybate) Jazz	Hikma [†]	0.5 g/mL oral solution	Treatment of cataplexy or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy	January 3, 2023

[†]180 days of marketing exclusivity

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Indications/Label updates

Drug name manufacturer(s)	Type	Description
Adacel [®] (tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine adsorbed) Sanofi	New indication	For immunization during the third trimester of pregnancy to prevent pertussis in infants younger than 2 months of age
Brukinsa [®] (zanubrutinib) BeiGene	New indication	Treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma
Enjaymo [™] (sutimlimab-jome) Sanofi	Updated indication	Treatment of hemolysis in adults with cold agglutinin disease

Drug name manufacturer(s)	Type	Description
Keytruda ® (pembrolizumab) Merck	New indication	As a single agent, as adjuvant treatment following resection and platinum-based chemotherapy for adult patients with Stage IB (T2a ≥ 4 cm), II, or IIIA non-small cell lung cancer
Odactra ™ House Dust Mite (<i>Dermatophagoides farinae</i> and <i>Dermatophagoides pteronyssinus</i>) ALK-Abello	Expanded indication	Immunotherapy for the treatment of house dust mite-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive <i>in vitro</i> testing for IgE antibodies to <i>Dermatophagoides farinae</i> or <i>Dermatophagoides pteronyssinus</i> house dust mites, or by positive skin testing to licensed house dust mite allergen extracts. Odactra is approved for use in persons 12 through 65 years of age.
Revatio ® (sildenafil) Viatis	Expanded indication	Treatment of pulmonary arterial hypertension to improve exercise ability and, in pediatric patients too young to perform standardized exercise testing, pulmonary hemodynamics thought to underly improvements in exercise in patients 1 to 17 years old
Tukysa ® (tucatinib) Seagen	New indication	In combination with trastuzumab, for the treatment of adult patients with RAS wild-type, HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy

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Drug recalls/Withdrawals/Shortages/Discontinuations

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
<p>Acyclovir Eugia</p>	<p>1000 mg per 20 mL (50 mg/mL) injection</p>	<p>Recall</p>	<p>Eugia announced a consumer level recall of a single lot of acyclovir 1000 mg/20 mL due to product complaint of “dark particles” inside the vial.</p> <p>Acyclovir injection is used for the treatment of herpes simplex infections in immunocompromised patients, initial episodes of herpes genitalis, herpes simplex encephalitis, neonatal herpes simplex virus infection, and varicella-zoster infections in immunocompromised patients.</p>
<p>Adlyxin® (lixisenatide) Sanofi</p>	<p>50 mcg/mL, 100 mcg/mL, 3 mL single-patient-use prefilled pen</p>	<p>Discontinuation</p>	<p>Sanofi announced that Adlyxin will no longer be available in the U.S. market. The discontinuation was a business decision and was not due to safety or efficacy issues.</p> <p>Adlyxin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.</p>
<p>Epinephrine Spectrum Laboratory</p>	<p>Bulk powder</p>	<p>Recall</p>	<p>Spectrum Laboratory announced a consumer level recall of three lots of epinephrine, a bulk active pharmaceutical ingredient used to manufacture or compound prescription products, due to product discoloration.</p> <p>Epinephrine bulk powder is used in manufacturing and compounding of finished dose epinephrine prescription products which can be used to treat a variety of medical conditions.</p>
<p>Lumoxiti® (moxetumomab pasudotox-tdfk) AstraZeneca</p>	<p>1 mg lyophilized cake or powder in a single-dose vial</p>	<p>Discontinuation</p>	<p>AstraZeneca announced plans to permanently discontinue Lumoxiti from the U.S. market by August 31, 2023. The discontinuation was a business decision and was not due to safety or efficacy issues.</p> <p>Lumoxiti is indicated for the treatment of adult patients with relapsed or refractory hairy cell leukemia who received at least two prior systemic therapies, including treatment with a purine nucleoside analog.</p>

Key guideline/Literature updates

Topic	Reference
Global Strategy for Prevention, Diagnosis and Management of Chronic Obstructive Pulmonary Disease – 2023 Report	<u>Global Initiative for Chronic Obstructive Lung Disease.</u> 2023
Nonpharmacologic and Pharmacologic Treatments of Adults in the Acute Phase of Major Depressive Disorder – American College of Physicians	<u>Annals of Internal Medicine.</u> January 2023
Pharmacologic Treatment of Primary Osteoporosis or Low Bone Mass to Prevent Fractures in Adults – American College of Physicians	<u>Annals of Internal Medicine.</u> January 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia - Version 3.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia.</u> January 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Anal Carcinoma - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma.</u> January 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas - Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas.</u> February 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer - Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer.</u> February 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma - Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma.</u> January 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer - Version 3.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer.</u> January 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers - Version 5.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers.</u> January 2023

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kidney Cancer - Version 4.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer.</u> January 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Hodgkin Lymphoma - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Hodgkin Lymphoma.</u> January 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas.</u> January 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer - Version 4.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer.</u> January 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma.</u> January 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: T-Cell Lymphomas - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas.</u> January 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Testicular Cancer - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Testicular Cancer.</u> January 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic - Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic.</u> January 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection.</u> January 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Antiemesis - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Antiemesis.</u> January 2023

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue - Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue.</u> January 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation - Version 3.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation.</u> January 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Palliative Care - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Palliative Care.</u> January 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Smoking Cessation - Version 3.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Smoking Cessation.</u> January 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adolescent and Young Adult (AYA) Oncology - Version 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Adolescent and Young Adult (AYA) Oncology.</u> January 2023

