

RxHighlights

June 2023

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New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Columvi [®] (glofitamab-gxbm)* Roche	Anti-CD20/CD3 T cell monoclonal antibody	Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified or large B-cell lymphoma arising from follicular lymphoma, after two or more lines of systemic therapy	June 26, 2023
Elevidys (delandistrogene moxeparvovec- rokl) [†] Sarepta Therapeutics	Gene therapy	Treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the <i>DMD</i> gene	June 30, 2023
Litfulo [™] (ritlecitinib)* Pfizer	Janus kinase inhibitor	Treatment of severe alopecia areata in adults and adolescents 12 years and older	July 7, 2023
Lodoco [®] (colchicine) Agepha Pharma	Alkaloid	To reduce the risk of myocardial infarction, stroke, coronary revascularization, and cardiovascular (CV) death in adult patients with established atherosclerotic disease or with multiple risk factors for CV disease	Second half of 2023
Ngenla [™] (somatrogon-ghla) ^{†*} Pfizer	Human growth hormone	Treatment of pediatric patients aged 3 years and older who have growth failure due to an inadequate secretion of endogenous growth hormone	August 2023
Roctavian [™] (valoctocogene roxaparvovec- rvox) [†] BioMarin	Gene therapy	Treatment of adults with severe hemophilia A (congenital factor VIII deficiency with factor VIII activity < 1 IU/dL) without antibodies to adeno-associated virus serotype 5 detected by an FDA-approved test	TBD

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Rystiggo® (rozanolixizumab-noli) [†] * UCB	Neonatal Fc receptor inhibitor	Treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor or anti-muscle-specific tyrosine kinase antibody positive.	June 30, 2023
Suflave® (polyethylene glycol 3350/sodium sulfate/potassium chloride/magnesium sulfate/sodium chloride) Braintree Laboratories	Osmotic laxative	Cleansing of the colon in preparation for colonoscopy in adults	June 30, 2023
Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) [†] Argenx	Neonatal Fc receptor antibody	Treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor antibody positive	June 22, 2023

*New molecular entity; †Orphan drug; 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
Aggrastat® (tirofiban) Medicure	Nexust, Glandt, Eugiat	5 mg/100 mL injection	Reduce the rate of thrombotic cardiovascular events in patients with non-ST elevation acute coronary syndrome	May 30, 2023 [^]
Noxafil® (posaconazole) Merck	Part	300 mg/16.7 mL (18 mg/mL) injection	Treatment of invasive aspergillosis and prophylaxis of invasive <i>Aspergillus</i> and <i>Candida</i> infections	June 29, 2023

Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Prezista® (darunavir) Janssen	Lupin [†] , Teva [†] , Viatrix [†]	600 mg, 800 mg tablets	In combination with other antiretroviral agents, for the treatment of human immunodeficiency virus infection	June 3, 2023

[†]A-rated generic manufacturer
[^]Launch date for Nexus; Launch dates for Gland12.5 mg/250 mL injection and Eugia 5 mg/100 mL and 12.5 mg/250 mL injection TBD
[±]Granted 180-days of competitive generic therapy exclusivity

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Indications/Label updates

Drug name manufacturer(s)	Type	Description
Bylvay® (odevixibat) Ipsen	New orphan indication	Treatment of cholestatic pruritus in patients 12 months of age and older with Alagille syndrome
Gavreto® (pralsetinib) Genentech and Blueprint Medicines	Indication withdrawal	The manufacturers announced they are voluntarily withdrawing the following indication: Treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic rearranged during transfection (RET)-mutant medullary thyroid cancer who require systemic therapy
Jardiance® (empagliflozin), and Synjardy® (empagliflozin/metformin) Eli Lilly	Expanded indication	As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus
Liletta® (levonorgestrel-releasing intrauterine system) AbbVie	New indication	Treatment of heavy menstrual bleeding for up to 5 years in patients who choose to use intrauterine contraception as their method of contraception
Linzess® (linaclotide) Ironwood Pharmaceuticals	New indication	Treatment of functional constipation in pediatric patients 6 to 17 years of age

Drug name manufacturer(s)	Type	Description
Lynparza® (olaparib) AstraZeneca	New indication	In combination with abiraterone and prednisone or prednisolone, for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated metastatic castration-resistant prostate cancer
Prevymis® (letermovir) Merck	New indication	Prophylaxis of cytomegalovirus disease in adult kidney transplant recipients at high risk
Talzenna® (talazoparib) Pfizer	New indication	Treatment of adult patients with homologous recombination repair gene-mutated metastatic castration-resistant prostate cancer
Triumeq/Triumeq PD (abacavir/dolutegravir/lamivudine) ViiV Healthcare	Expanded indication	Treatment of HIV-1 infection in adults and in pediatric patients aged at least 3 months and weighing at least 6 kg

Drug safety news / Drug updates

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Drug name manufacturer(s)	Description
COVID-19 vaccines	The FDA’s Vaccines and Related Biological Products Advisory Committee unanimously voted for the 2023-2024 formula of COVID-19 vaccines in the U.S to include a periodic update of the current vaccine composition to a monovalent XBB-lineage.
Leqembi™ (lecanemab-irmb) Eisai/Biogen	The FDA convened a Peripheral and Central Nervous System Drugs Advisory Committee meeting to discuss Eisai/Biogen’s Leqembi for the treatment of early Alzheimer’s disease. The FDA Advisory Committee reviewed Eisai’s supplemental Biologics License Application to convert the accelerated approval to a traditional (full) approval.
RSV vaccines	The CDC’s Advisory Committee on Immunization Practices voted to recommend that adults aged 60 years and older may receive a single dose of a respiratory syncytial virus (RSV) vaccine, using shared clinical decision-making based on risk assessment.

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Drug recalls/Withdrawals/Shortages/Discontinuations

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Contour® Next Gen Blood Glucose Meters Ascensia Diabetes Care	n/a	Recall	Ascensia Diabetes Care announced a voluntary consumer-level recall of specific serial numbers of one lot of Contour Next Gen Blood Glucose Meters due to potentially incorrect units of measurement. The recalled meters had incorrect factory-set units of measurement where the meters display glucose results in mmol/L rather than mg/dL.

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
<p>Dronabinol and ziprasidone Major Pharmaceutical, Rugby Laboratories</p>	<p>dronabinol 2.5 mg capsules, ziprasidone 20 mg capsules</p>	<p>Recall</p>	<p>The FDA announced a consumer level recall of a single lot of Major Pharmaceutical's and Rugby Laboratories' dronabinol capsules and ziprasidone capsules. Some unit dose cartons labeled as ziprasidone 20 mg capsules were found to contain blister packages labeled as and containing dronabinol 2.5 mg capsules. Dronabinol 2.5 mg capsules may be in outer cartons that read dronabinol or ziprasidone.</p> <p>Ziprasidone is used for the treatment of schizophrenia, bipolar manic or mixed episodes, and as adjunctive therapy for the treatment of bipolar disorder.</p> <p>Dronabinol is used for the treatment of anorexia associated with weight loss in patients with Acquired Immune Deficiency Syndrome, and nausea and vomiting associated with chemotherapy.</p>
<p>Oxandrin® (oxandrolone) and oxandrolone Gemini, Upsher-Smith, Par, Sandoz</p>	<p>2.5 mg and 10 mg tablets</p>	<p>Withdrawal</p>	<p>The FDA announced the final decision to withdraw approval of brand and generic Oxandrin. The FDA believes a potential problem associated with oxandrolone tablets is sufficiently serious that the drug products should be removed from the market.</p>

Key guideline/Literature updates

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Version - 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma.</u> June 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kidney Cancer Version - 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer.</u> June 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma Version - 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma.</u> June 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Systemic Mastocytosis Version - 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Systemic Mastocytosis.</u> June 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis Version - 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis.</u> June 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prevention and Treatment of Cancer-Related Infections Version - 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Prevention and Treatment of Cancer-Related Infections.</u> June 2023

