

RxHighlights

July 2023

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New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Beyfortus™ (nirsevimab-alip) Sanofi, AstraZeneca	Anti-RSV monoclonal antibody D25	Prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in neonates and infants born during or entering their first RSV season; Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season	August 7, 2023
Opill® (norgestrel)± Perrigo	Contraceptive	Prevent pregnancy	Early 2024
RiVive™ (naloxone) ± 3 mg nasal spray Harm Reduction Therapeutics	Opioid antagonist	Revive someone during an overdose from many prescription pain medications or street drugs such as heroin	Early 2024
Vanflyta® (quizartinib)† Daiichi Sankyo	FLT-3 receptor tyrosine kinase inhibitor	In combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia that is FLT3 internal tandem duplication positive as detected by an FDA-approved test	July 26, 2023
Xdemvy™ (lotilaner) Tarsus	Antagonist of insect and arachnid GABA-Cl channels	Treatment of <i>Demodex</i> blepharitis	End of August 2023
Ycanth™ (cantharidin) Verrica Pharmaceuticals	Vesicant (blistering agent)	Topical treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older	August 1, 2023

*New molecular entity; †Orphan drug; ±Prescription to over-the-counter approval

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New generics

Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Mozobil [®] (plerixafor) Sanofi/Genzyme	Amneal [†] , Eugia [†] , Meitheal/Kindros [†] , Novadoz/MSN [†] , Teva [†]	24 mg/ 1.2 mL (20 mg/mL) subcutaneous solution	In combination with granulocyte-colony stimulating factor to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma or multiple myeloma	July 24, 2023
Symbicort [®] (budesonide/formoterol) AstraZeneca	Viatis/Kindeva (Breyne [™]) [†]	80 mcg/ 4.5 mcg, 160 mcg/ 4.5 mcg inhalation aerosol	Asthma; chronic obstructive pulmonary disease	July 31, 2023

[†]A-rated generic manufacturer

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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
Mozobil [®] (plerixafor) Sanofi/Genzyme	Fresenius Kabi	24 mg/ 1.2 mL (20 mg/mL) subcutaneous solution	In combination with granulocyte-colony stimulating factor to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma or multiple myeloma	July 11, 2023

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Indications/Label updates

Drug name manufacturer(s)	Type	Description
Jemperli [®] (dostarlimab-gxly) GSK	New indication	In combination with carboplatin and paclitaxel, followed by Jemperli as a single agent for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient, as determined by an FDA-approved test, or microsatellite instability-high
Leqembi [®] (lecanemab-irmb) Eisai/Biogen	Full approval	The FDA announced the traditional approval of Leqembi, for the treatment of Alzheimer's disease. It was previously approved via the accelerated approval pathway. CMS also announced that Medicare coverage for Leqembi, as outlined in the National Coverage Determination guidance, is through enrollment in a registry-based study. Prior to traditional approval, Leqembi was restricted to patients enrolled in a clinical study.
Leqvio [®] (inclisiran) Novartis	Updated indication	An adjunct to diet and statin therapy for the treatment of adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia, to reduce low-density lipoprotein cholesterol
Nucynta [®] (tapentadol) Collegium Pharmaceutical	Expanded indication	Management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults and pediatric patients aged 6 years and older with a body weight of at least 40 kg
Wegovy [®] (semaglutide) Novo Nordisk	Updated dosing	The FDA approved an update to the drug label for Wegovy to include 1.7 mg weekly as an additional maintenance dose for use as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index of 30 kg/m ² or greater (obesity), or 27 kg/m ² or greater (overweight) in the presence of at least one weight-related comorbid condition.

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Drug safety news / Drug updates

Drug name manufacturer(s)	Description
<p>Leqembi™ (lecanemab-irmb) Eisai and Biogen</p>	<p>The FDA announced the traditional approval of Eisai/Biogen’s Leqembi , for the treatment of Alzheimer’s disease. Treatment with Leqembi should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. Leqembi was previously approved for this indication via the accelerated approval pathway.</p>

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Drug recalls/Withdrawals/Shortages/Discontinuations

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
<p>Albuterol inhalation aerosol Cipla</p>	<p>90 mcg (200 metered inhalation)</p>	<p>Recall</p>	<p>The FDA announced a consumer-level recall of six lots of Cipla’s albuterol inhalation aerosol because of a complaint for one inhaler where leakage was observed through the inhaler valve.</p> <p>Albuterol is indicated for the treatment and prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise induced bronchospasm.</p>
<p>Sodium chloride injection B. Braun Medical</p>	<p>0.9% injection in EXCEL plus IV container, 1000 mL</p>	<p>Recall</p>	<p>B. Braun Medical announced a consumer-level recall of some lots of sodium chloride 0.9% injection due to potential of the bags to leak compromising the sterility of the product.</p> <p>Sodium chloride injection is indicated for use in adults and pediatric patients as sources of electrolytes and water for hydration; extracellular fluid replacement, treatment of metabolic alkalosis in the presence of fluid loss and mild sodium depletion; use as a priming solution in hemodialysis procedures and may be used to initiate and terminate blood transfusions without hemolyzing red blood cells; use as pharmaceutical aids and diluents for the infusion of compatible drug additives</p>

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
<p>Tydemy™ (drospirenone/ethinyl estradiol and levomefolate) Lupin</p>	<p>3 mg/0.03 mg/0.451 mg and 0.451 mg tablets</p>	<p>Recall</p>	<p>Lupin announced a consumer level recall of two lots of Tydemy because of an out of specification result observed in inactive content and results of an impurity test.</p> <p>Tydemy is indicated for use by women to prevent pregnancy. It is also indicated in women who choose to use an oral contraceptive as their method of contraception, to raise folate levels for the purpose of reducing the risk of a neural tube defect in a pregnancy conceived while take the product or shortly after discontinuing the product.</p>

Key guideline/Literature updates

Topic	Reference
<p>National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia Version - 2.2023</p>	<p><u>NCCN Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia.</u> July 2023</p>
<p>National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia Version 4.2023</p>	<p><u>NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia.</u> July 2023</p>
<p>National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas Version 5.2023</p>	<p><u>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas.</u> July 2023</p>
<p>National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia Version 1.2024</p>	<p><u>NCCN Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia.</u> July 2023</p>
<p>National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Mesothelioma: Peritoneal Version 2.2023</p>	<p><u>NCCN Clinical Practice Guidelines in Oncology: Mesothelioma: Peritoneal.</u></p>

Topic	Reference
	July 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions.</u> July 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer.</u> July 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer Version 4.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer.</u> July 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thyroid Carcinoma Version 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma.</u> July 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Lung Cancer Screening Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Lung Cancer Screening.</u> July 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adult Cancer Pain Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain.</u> July 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adolescent and Young Adult (AYA) Oncology Version 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Adolescent and Young Adult (AYA) Oncology.</u> July 2023

