

RxHighlights

August 2023

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New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Akeega™ (niraparib/abiraterone) [†] Janssen	Poly (ADP-ribose) polymerase inhibitor/ CYP17 inhibitor	Treatment of adult patients with deleterious or suspected deleterious BRCA-mutated metastatic castration-resistant prostate cancer	TBD
Eylea® HD (aflibercept) Regeneron	Vascular endothelial growth factor inhibitor	Treatment of neovascular (wet) age-related macular degeneration, diabetic macular edema, and diabetic retinopathy	August 22, 2023
Elrexfio™ (elranatamab-bcmm) ^{†*} Pfizer	BCMA CD3-targeted bispecific antibody	Treatment of adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody	August 16, 2023
Focinvez™ (fosaprepitant) Spes Pharmaceuticals	Substance P/neurokinin-1 receptor antagonist	In combination with other antiemetic agents, in adults and pediatric patients 6 months of age and older for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy including high-dose cisplatin; delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy	TBD
Hepzato Kit™ (melphalan/hepatic delivery system) [†] Decath	Phenylalanine mustard	Liver-directed treatment for adults with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation	4 th Quarter 2023
Izervay™ (avacincaptad pegol) [*] Astellas, IVERIC bio	C5 complement inhibitor	Treatment of geographic atrophy secondary to age-related macular degeneration	August 10, 2023

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Sohonos™ (palovarotene) [†] Ipsen	Selective retinoic acid receptor agonist	Reduction in volume of new heterotopic ossification in adults and pediatric patients aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva	August 30, 2023
Talvey™ (talquetamab-tgvs) [†] Janssen	GPRC5D/CD3 monoclonal antibody	Treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody	August 14, 2023
Veopoz™ (pozelimab-bbfg) [†] Regeneron	C5a receptor inhibitor	Treatment of adult and pediatric patients 1 year of age and older with CD55-deficient protein-losing enteropathy, also known as CHAPLE disease	August 23, 2023
Zurzuvae™ (zuranolone)* Biogen, Sage Therapeutics	GABA-A receptor allosteric modulator	Treatment of postpartum depression in adults	4 th Quarter 2023

*New molecular entity; †Orphan drug; ‡New prescription to over-the-counter approval; TBD: To be determined

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New biosimilars

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Tyruko® (natalizumab-sztn) Polypharma Biologics, Sandoz	Alpha-4-integrin inhibitor	As monotherapy for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease, in adults; For inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of tumor necrosis factor-alpha	2025

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New generics

Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Balcoltra™ (levonorgestrel/ethinyl estradiol and ferrous bisglycinate) Avion	Xiromed ^{†*}	0.1 mg/ 0.02 mg/ 36.5 mg tablets	Pregnancy prevention	August 17, 2023
Kombiglyze® XR (saxagliptin/metformin, extended release) AstraZeneca	Viartis [†] , Sun [†] and Dr. Reddy's [†]	2.5 mg/1 g, 5 mg/500 mg, 5 mg/1 g tablets	Type 2 diabetes mellitus	August 9, 2023 [^]
Onglyza® (saxagliptin) AstraZeneca	Viartis [†] , Aurobindo [†] , Glenmark [†] and Sun [†]	2.5 mg, 5 mg tablets	Type 2 diabetes mellitus	August 1, 2023 [‡]
Spiriva® HandiHaler® (tiotropium) Boehringer Ingelheim	Lupin ^{†*}	18 mcg inhalation capsules	Maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease , including chronic bronchitis and emphysema	August 16, 2023
Vyvance® (lisdexamfetamine) Takeda	Norwich/Alvogen [†] , Hikma [†] , Sun ^{†§} , Solco/Prinston [†] , Amneal [†] and Viartis [†]	10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg capsules 10 mg, 20 mg, 30 mg, 40 mg 50 mg and 60 mg chewable tablets	Attention deficit hyperactivity disorder; and binge eating disorder	August 25, 2023

[†]A-rated generic manufacturer

^{*}Branded generic marketed as Joyeaux[®]

^{*}180-days of generic exclusivity

[^]Viartis launched 8/9/2023 and Dr. Reddy's launched 8/10/2023. Sun's launch plans TBD

[‡]Aurobindo and Viartis launched 8/1/2023 and Glenmark launched 8/8/2023. Sun's launch plans TBD

[§]Sun launched chewable tablets on 8/25/23

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Indications/Label updates

Drug name manufacturer(s)	Type	Description
Abrysvo™ (respiratory syncytial virus vaccine) Pfizer	New indication	Active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus in infants from birth through 6 months of age
Daxxify® (daxibotulinumtoxinA-ianm) Revanche Therapeutics	New orphan indication	Treatment of cervical dystonia in adults
Ilaris® (canakinumab) Novartis	New indication	Symptomatic treatment of adults with gout flares in whom non-steroidal anti-inflammatory drugs and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate
Ingrezza® (valbenazine) Neurocrine Biosciences	New indication	Treatment of adults with chorea associated with Huntington's disease
Lonsurf® (trifluridine/tipiracil) Taiho Oncology, Taiho Pharmaceutical	Expanded indication	A single agent or in combination with bevacizumab, for the treatment of adult patients with metastatic colorectal cancer previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy
Mekinist® (trametinib) plus Tafinlar® (dabrafenib) Novartis	Expanded indication	Treatment of adult and pediatric patients 1 year of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options
Prevymis® (letermovir) Merck	Updated label	To allow for extension of the dosing regimen from 100 to 200 days post-transplant for the prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV seropositive recipients (R+) of an allogeneic hematopoietic stem cell transplant who are at risk for late CMV infection and disease

Drug name manufacturer(s)	Type	Description
Reblozyl® (luspatercept-aamt) Bristol Myers Squibb	Expanded indication	Treatment of anemia without previous erythropoiesis stimulating agent use in adults with very low- to intermediate-risk myelodysplastic syndromes who may require regular red blood cell transfusions

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Drug recalls/Withdrawals/Shortages/Discontinuations

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Cromolyn oral solution Ritedose	100 mg/ 5 mL	Recall	<p>The FDA announced a consumer level recall of one lot of cromolyn oral solution because of manufacturing issues related to an alternative source of drug. Product was manufactured and released for dispensing prior to final FDA approval.</p> <p>Cromolyn oral solution is indicated in the management of patients with mastocytosis.</p>
Digoxin tablets Marlex	0.125 mg, 0.25 tablets	Recall	<p>Marlex announced a consumer level recall of one lot of digoxin 0.125 mg and one lot of digoxin 0.25 mg tablets because of a label mix-up. Bottles of digoxin 0.125 mg are incorrectly labeled and contain digoxin 0.25 mg tablets. Bottles of digoxin 0.25 mg tablets are incorrectly labeled and contain digoxin 0.125 mg tablets.</p> <p>Digoxin is indicated for the treatment of heart failure and atrial fibrillation.</p>
Sodium chloride injection B. Braun Medical	0.9% sodium chloride injection in EXCEL plus IV container, 1000 mL	Recall	<p>B. Braun Medical announced a consumer-level recall of one lot of sodium chloride 0.9% injection due to a portion of the label to be missing or partially printed.</p> <p>Sodium chloride injection is indicated for use as a source of electrolytes and water for hydration; extracellular fluid replacement, treatment of metabolic alkalosis; priming solution in hemodialysis</p>

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
			procedures, and for blood transfusions; and a as pharmaceutical aids and diluents

Key guideline/Literature updates

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bone Cancer - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Bone Cancer.</u> August 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers - Version 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers.</u> August 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastric Cancer - Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer.</u> August 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Histiocytic Neoplasms - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Histiocytic Neoplasms.</u> August 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma - Version 4.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma.</u> August 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms - Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms.</u> August 2023

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia.</u> August 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer - Version 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer.</u> August 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer.</u> August 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Systemic Mastocytosis - Version 4.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Systemic Mastocytosis.</u> August 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thyroid Carcinoma - Version 4.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma.</u> August 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic.</u> August 2023

