

RxHighlights

September 2023

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New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Aphexda™ (motixafortide) [†] BioLineRx	Selective chemokine receptor 4 inverse agonist	In combination with filgrastim to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma	September 20, 2023
Comirnaty® (Omicron XBB.1.5) 2023 - 2024 Pfizer/BioNTech's	Vaccine	COVID-19 vaccines in individuals 12 years of age and older as a single dose at least 2 months since the last dose of any COVID-19 vaccine	September 11, 2023
Spikevax® (Omicron XBB.1.5) 2023 - 2024 Moderna			
Entyvio® (vedolizumab) subcutaneous injection Takeda	Integrin receptor antagonist	Maintenance treatment of moderately to severely active ulcerative colitis	October 5, 2023
Exxua (gepirone)* Fabre-Kramer Pharmaceuticals	Serotonin single receptor (1A) agonist	Treatment of major depressive disorder in adults	TBD
Likmez™ (metronidazole) Appili Therapeutics	Nitroimidazole	Treatment of symptomatic trichomoniasis caused by <i>Trichomonas vaginalis</i> in adult females and males when the diagnosis is confirmed by appropriate laboratory procedures; asymptomatic trichomoniasis caused by <i>Trichomonas vaginalis</i> in adult females when the organism is associated with endocervicitis, cervicitis, or cervical erosion; acute intestinal amebiasis (amoebic dysentery) and amebic liver abscess in adults and pediatric patients; several other serious infections caused by susceptible anaerobic bacteria in adults	TBD

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Ojjaara (mometinib) [†] GSK	Janus kinase inhibitor	Treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia.	September 20, 2023
Pombiliti [™] (cipaglucosidase alfa-atga) ^{†*} plus Opfolda [™] (miglustat) Amicus Therapeutics	Enzyme therapy	Treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥ 40 kg and who are not improving on their current enzyme replacement therapy	October 4, 2023
Rivfloza [™] (nedosiran) ^{†*} Novo Nordisk	Glycolate oxidase antagonist	To lower urinary oxalate levels in children 9 years of age and older and adults with primary hyperoxaluria type 1 and relatively preserved kidney function	Early 2024
Xalkori [®] (crizotinib) oral pellet Pfizer	Kinase inhibitor	Treatment of adult patients with metastatic non-small cell lung cancer whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive as detected by an FDA-approved test; Pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma that is ALK-positive; Adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor that is ALK-positive.	TBD

*New molecular entity; †Orphan drug; TBD: To be determined

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New biosimilars

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Tofidence [™] (tocilizumab-bavi) Biogen	Interleukin-6 (IL-6) receptor inhibitor	Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs; Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis; Patients 2 years of age and older with active systemic juvenile idiopathic arthritis	TBD

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New generics

Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Alphagan® P (brimonidine) Allergan	Alembic†, Apotex†	0.1% ophthalmic solution	Lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension	September 2, 2023 [^]
Retin-A Micro® (tretinoin) Bausch Health	Encube†	0.08% topical gel	Acne vulgaris	September 6, 2023

†A-rated generic manufacturer
[^] Alembic launch plans TBD

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Indications/Label updates

Drug name manufacturer(s)	Type	Description
Bosulif® (bosutinib) Pfizer	Expanded indication, formulation approval	Treatment of adult and pediatric patients 1 year of age and older with chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia, newly-diagnosed or resistant or intolerant to prior therapy The FDA also approved a new capsule formulation of Bosulif.
COVID-19 vaccine Pfizer/BioNTech and Moderna	Emergency Use Authorization (EUA)	The FDA granted EUA to Pfizer/BioNTech's COVID-19 vaccine (2023-2024 formula) and Moderna's COVID-19 vaccine (2023-2024 formula) in individuals from 6 months to 11 years of age
Jardiance® (empagliflozin) Eli Lilly	New indication	To reduce the risk of sustained decline in estimated glomerular filtration rate, end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression
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

Drug name manufacturer(s)	Type	Description
Temodar® (temozolomide) Merck	Updated indication	Adjuvant treatment of adults with newly diagnosed anaplastic astrocytoma and treatment of adults with refractory anaplastic astrocytoma

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Drug recalls/Withdrawals/Shortages/Discontinuations

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Betaxolol tablets KVK Tech	10 mg tablets	Recall	KVK Tech announced a consumer-level recall of one lot of betaxolol tablets because of the presence of a single foreign tablet. Betaxolol is indicated in the management of hypertension.
Brexafemme® (ibrexafungerp) Scynexis	150 mg blister packs	Recall	Scynexis announced a consumer-level recall of two lots of Brexafemme due to potential cross contamination with a non-antibacterial beta-lactam drug substance in the ibrexafungerp citrate used to manufacture the Brexafemme tablets. Brexafemme is indicated in adult and post-menarchal pediatric females for the treatment of vulvovaginal candidiasis and for the reduction in the incidence of recurrent vulvovaginal candidiasis.
Sandimmune® (cyclosporine) Novartis	100 mg/mL oral solution	Recall	Novartis announced a consumer level recall of one lot of Sandimmune oral solution because of crystal formation observed in some bottles, which could potentially result in incorrect dosing. No other Sandimmune formulations are impacted. Sandimmune is indicated for the prophylaxis of organ rejection in kidney, liver, and heart allogeneic transplants.

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Sodium injection and lidocaine injection Hospira	Sodium bicarbonate 4.2% injection Lidocaine 1% and 2% injection	Recall	Hospira announced a user-level recall of one lot of sodium bicarbonate injection and two lots of lidocaine hydrochloride injection products because of the potential for presence of glass particulate matter. Sodium bicarbonate injection is indicated in the treatment of metabolic acidosis, treatment of certain drug intoxications, and severe diarrhea. Lidocaine hydrochloride injection is indicated in the acute management of ventricular arrhythmias.
Sucralfate oral suspension VistaPharm	1 gram/10 mL oral suspension	Recall	VistaPharm announced a consumer-level recall of one lot of sucralfate oral suspension due to <i>Bacillus cereus</i> contamination. Sucralfate oral suspension is indicated in the short-term treatment of active duodenal ulcer.
Vyvanse® (lisdexamfetamine) Various manufacturers	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	Shortage	Brand and generic Vyvanse are in shortage due to increased demand and limited availability of active ingredient due to quotas set by the Drug Enforcement Agency (DEA) for controlled substances. Both capsules and chewable tablets are in short supply. Vyvanse is FDA-approved for the treatment of attention deficit hyperactivity disorder and binge-eating disorder.

Key guideline/Literature updates

Topic	Reference
American Heart Association/American College of Cardiology – Management of Patients with Chronic Coronary Disease	<u>Circulation</u> . July 2023
European Society of Cardiology - Management of Acute Coronary Syndromes	<u>European Heart Journal</u> . August 2023
European Society of Cardiology – Diagnosis and Treatment of Acute and Chronic Heart Failure	<u>European Heart Journal</u> . October 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia - Version 5.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia</u> . September 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Anal Carcinoma - Version 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma</u> . September 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer - Version 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer</u> . September 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cervical Cancer - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Cervical Cancer</u> . September 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer - Version 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer</u> . September 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatocellular Carcinoma - Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Hepatocellular Carcinoma</u> . September 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kaposi Sarcoma - Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Kaposi Sarcoma</u> . September 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma</u> .

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	September 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Occult Primary - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Occult Primary.</u> September 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer - Version 4.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer.</u> September 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer - Version 5.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer.</u> September 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> September 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Uterine Neoplasms - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms.</u> September 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Vulvar Cancer - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Vulvar Cancer.</u> September 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma.</u> September 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic - Version 2.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic.</u> September 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection - Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection.</u> September 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation - Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation.</u>

Topic	Reference
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National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Smoking Cessation Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Smoking Cessation.</u> September 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer in People with HIV - Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Cancer in People with HIV.</u> September 2023



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