

RxHighlights

December 2022

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New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Adstiladrin [®] (nadofaragene firadenovec-vncg) Ferring Pharmaceuticals	Gene therapy	Treatment of adult patients with high-risk Bacillus Calmette-Guérin unresponsive non-muscle invasive bladder cancer with carcinoma in situ with or without papillary tumors	Second half of 2023
Briumvi [™] (ublituximab-xiyy)* TG Therapeutics	Anti-CD-20 monoclonal antibody	Treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults	December 29, 2022
Krazati [™] (adagrasib) ^{†*} Mirati Therapeutics	KRAS inhibitor	Treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer, as determined by an FDA-approved test, who have received at least one prior systemic therapy	December 14, 2022
Iyuzeh [™] (latanoprost) Thea Pharma	Prostaglandin F2α analogue	Reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	Second half of 2023
Lunsumio [™] (mosunetuzumab-axgb) Genentech	Anti-CD20/CD3 monoclonal antibody	Treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy	December 28, 2022
NexoBrid [®] (anacaulase-bcdb) ^{†*} MediWound	Peptide hydrolase replacement agent	Eschar removal in adults with deep partial thickness and/or full thickness thermal burns	2 nd Quarter 2023

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Olpruva™ (sodium phenylbutyrate) Acer Therapeutics, Relief Therapeutics	Nitrogen-binding agent	Adjunctive therapy to standard of care, which includes dietary management, for the chronic management of adult and pediatric patients weighing 20 kg or greater and with a body surface area of 1.2 m ² or greater, with urea cycle disorders involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase, or argininosuccinic acid synthetase	TBD
Rezlidhia™ (olutasidenib) ^{†*} Rigel Pharmaceuticals	Dehydrogenase 1 inhibitor	Treatment of adult patients with relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 mutation as detected by an FDA-approved test	December 6, 2022
Sunlenca® (lenacapavir)* Gilead Sciences	HIV capsid inhibitor	In combination with other antiretroviral(s), for the treatment of human immunodeficiency virus 1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations	December 28, 2022

*New molecular entity; †Orphan drug

New biosimilars

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Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Idacio® (adalimumab-aacf) Fresenius Kabi	Tumor necrosis factor	Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult and pediatric Crohn's disease, ulcerative colitis, and plaque psoriasis	July 2023

New generics

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Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Hetlio[®] (tasimelteon) Vanda	Teva [†] , Apotex [†]	20 mg capsules	Non-24-hour sleep-wake disorder and nighttime sleep disturbances in Smith-Magenis Syndrome	December 29, 2022 [§]
Treanda[®] (bendamustine) Cephalon/Teva	Accord Healthcare [†] , Dr. Reddy's [†]	25 mg and 100 mg vials for injection	Chronic lymphocytic leukemia and indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen	December 7, 2022 [*]

†A-rated generic manufacturer

*Launch date for Accord, TBD for Dr. Reddy's; §Launch date for Teva, TBD for Apotex

Indications/Label updates

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Drug name manufacturer(s)	Type	Description
Actemra[®] (tocilizumab) Genentech	New indication	Treatment of hospitalized adult patients with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation
Avycaz[®] (ceftazidime/avibactam) Allergan	Expanded indication	Treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia in adult and pediatric patients aged 3 months and older caused by the following susceptible gram-negative microorganisms: <i>Klebsiella pneumoniae</i> , <i>Enterobacter cloacae</i> , <i>Escherichia coli</i> , <i>Serratia marcescens</i> , <i>Proteus mirabilis</i> , <i>Pseudomonas aeruginosa</i> , and <i>Haemophilus influenzae</i>
Brexafemme[®] (ibrexafungerp) Scynexis	New indication	Reduction in the incidence of recurrent vulvovaginal candidiasis

Drug name manufacturer(s)	Type	Description
COVID-19 vaccines Moderna, Pfizer/BioNTech	Expanded indication	The Centers for Disease Control and Prevention (CDC) expanded the use of updated (bivalent) COVID-19 vaccines for children ages 6 months through 5 years.
Keytruda® (pembrolizumab) Merck	Accelerated approval to full approval	The FDA approved Keytruda, for an alternate dosing regimen of 400 mg every six weeks for all approved adult solid tumor indications. The alternate dosing regimen was previously approved under accelerated approval in 2020. This converts the accelerated approval to full approval. Two indications, adult classical Hodgkin lymphoma and adult primary mediastinal large B cell lymphoma, for the alternate dosing regimen continue to be approved under accelerated approval.
Ibrance® (palbociclib) Pfizer	Updated indication	Treatment of adult patients with hormone receptor positive, human epidermal growth factor receptor 2 negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy
Pemfexy™ (pemetrexed) Eagle Pharmaceuticals	New indication	In combination with Keytruda® (pembrolizumab) and platinum chemotherapy, for the initial treatment of patients with metastatic non-squamous non-small cell lung cancer, with no EGFR or ALK genomic tumor aberrations.
Rubraca® (rucaparib) Clovis Oncology	Indication update	Restricting the maintenance treatment of recurrent ovarian cancer indication to only the patient population with a deleterious BRCA mutation (germline and/or somatic)
Tascenso ODT® (fingolimod) Cycle Pharmaceuticals	Expanded indication, new strength	Treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older To support the expanded indication, the FDA approved a new 0.5 mg strength of Tascenso ODT.
Tecentriq® (atezolizumab) Genentech	New orphan indication	As a single agent, for the treatment of adult and pediatric patients 2 years of age and older with unresectable or metastatic alveolar soft part sarcoma

Drug name manufacturer(s)	Type	Description
Tymlos® (abaloparatide) Radius Health	New indication	To increase bone density in men with osteoporosis at high risk for fracture (defined as a history of osteoporotic fracture or multiple risk factors for fracture), or patients who have failed or are intolerant to other available osteoporosis therapy.
Vraylar® (cariprazine) AbbVie	New indication	Adjunctive therapy to antidepressants for the treatment of major depressive disorder in adults
Wegovy® (semaglutide) Novo Nordisk	Expanded indication	Chronic weight management in pediatric patients aged 12 years and older with an initial body mass index at the 95th percentile or greater for age and sex
Xeloda® (capecitabine) Genentech	New indications	Treatment of adults with unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer as a component of a combination chemotherapy regimen; Treatment of adults with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease as a component of a combination regimen; Adjuvant treatment of adults with pancreatic adenocarcinoma as a component of a combination chemotherapy regimen
	Expanded indications	Adjuvant treatment of patients with Stage III colon cancer as a single agent or as a component of a combination chemotherapy regimen; perioperative treatment of adults with locally advanced rectal cancer as a component of chemoradiotherapy; treatment of patients with unresectable or metastatic colorectal cancer as a single agent or as a component of a combination chemotherapy regimen
Zejula® (niraparib) GSK	Indication update	Maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy

Drug recalls/Withdrawals/Shortages/Discontinuations

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Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Acyclovir injection Eugia	1000 mg per 20 mL (50 mg/mL)	Recall	<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>
Amoxicillin oral products Various manufacturers	125 mg/5 mL, 200 mg/5 mL, 250 mg/ 5 mL, 400 mg/5 mL oral powder for suspension	Shortage	<p>The FDA reports a national shortage of amoxicillin oral suspension products from multiple manufacturers due to increased demand. There is some supply available, but it may be either on allocation or have limited availability. The estimated time frame of product availability ranges from Q1 2023 through April 2023. Supply of other antibiotic medications are available as alternatives.</p>
Daptomycin injection Accord Healthcare	350 mg/vial, 500 mg/vial injection	Recall	<p>The FDA announced a consumer level recall of a single lot of Accord Healthcare’s daptomycin 500 mg/vial injection and a single lot of daptomycin 350 mg/vial injection due to a complaint report from a hospital pharmacy that vials labeled as “daptomycin for injection 500 mg/vial” were found in cartons labeled as “daptomycin for injection 350 mg/vial”.</p> <p>Daptomycin is used for the treatment of complicated skin and skin structure infections caused by certain susceptible isolates of Gram-positive bacteria.</p>
Quinapril Lupin	20 mg and 40 mg tablets	Recall	<p>The FDA announced a consumer level recall of four lots of Lupin’s quinapril tablets due to the presence of a nitrosamine impurity, N-Nitroso-Quinapril, above the acceptable daily intake level.</p>
Generic Tamiflu® (oseltamivir) Various manufacturers	30 mg, 45 mg, and 75 mg capsules; 6 mg/mL oral suspension	Shortage	<p>The supply of generic Tamiflu, used to treat influenza, is being monitored by the FDA and American Society of Health-System Pharmacists, who are working closely to share drug supply information. Although oseltamivir has experienced some supply disruptions, product is available from both brand and generic</p>

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			<p>manufacturers. However, there may be periodic local outages of product in retail.</p> <p>The U.S. Department of Health & Human Services (HHS) has been tracking the increased demand and resulting shortage of Tamiflu during this winter season. To ease the shortage of drug, HHS is giving local U.S. jurisdictions access to additional supplies of Tamiflu in the government-sponsored Strategic National Stockpile.</p>

Key guideline/Literature updates

Topic	Reference
Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults - International Antiviral Society - USA Panel	<i>Journal of the American Medical Association</i> . December 2022
Diagnosis and Management of Aortic Disease - American Heart Association/American College of Cardiology	<i>Journal of the American College of Cardiology</i> . November 2022
National Institutes of Health – COVID-19 Treatment	<i>COVID-19 Treatment Guidelines</i> . December 2022
Opioids for Pain – Centers for Disease Control and Prevention	<i>Morbidity and Mortality Weekly Report</i> . November 2022
Standards of Care in Diabetes – American Diabetes Association	<i>Diabetes Care</i> . January 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Ampullary Adenocarcinoma - Version 2.2022	<i>NCCN Clinical Practice Guidelines in Oncology: Ampullary Adenocarcinoma</i> . December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer - Version 3.2022	<i>NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer</i> . December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cervical Cancer - Version 1.2023	<i>NCCN Clinical Practice Guidelines in Oncology: Cervical Cancer</i> . December 2022

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Dermatofibrosarcoma Protuberans - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Dermatofibrosarcoma Protuberans.</u> December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers - Version 5.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers.</u> December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia.</u> December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Head and Neck Cancers - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers.</u> December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers - Version 4.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers.</u> December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kaposi Sarcoma - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Kaposi Sarcoma.</u> December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous.</u> December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Mesothelioma: Peritoneal - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Mesothelioma: Peritoneal.</u> December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Mesothelioma: Pleural - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Mesothelioma: Pleural.</u> December 2022

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma - Version 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma.</u> December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors.</u> December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</u> December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Occult Primary - Version 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Occult Primary.</u> December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer.</u> December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma.</u> December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer - Version 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer.</u> December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thymomas and Thymic Carcinomas - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Thymomas and Thymic Carcinomas.</u> December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Uterine Neoplasms - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms.</u> December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Vulvar Cancer - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Vulvar Cancer.</u>

Topic	Reference
	December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue.</u> December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Distress Management - Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Distress Management.</u> December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer in People with HIV - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Cancer in People with HIV.</u> December 2022



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