

RxHighlights

March 2022

New drugs

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Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Adlarity [®] (donepezil) Corium	Acetylcholinesterase inhibitor	Treatment of mild, moderate, and severe dementia of the Alzheimer's type	Early Fall 2022
Hyftor [™] (sirolimus) [†] topical gel Nobelpharm	mTOR inhibitor immunosuppressant	Treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years of age and older	TBD
Loreev XR [®] (lorazepam) 1.5 mg extended-release capsule Almatica	Benzodiazepine	Treatment of anxiety disorders in adults who are receiving stable, evenly divided, three times daily dosing with lorazepam tablets	March 15, 2022
Mayzent [®] (siponimod) 1 mg tablet and starter pack with seven 0.25 mg tablets Novartis	Selective sphingosine-1 phosphate receptor modulator	Treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults	March 17, 2022
Nexiclon ^{™ XR} (clonidine) 0.17 mg extended-release tablet Athena Bioscience	Alpha-2 agonist	Treatment of hypertension	March 9, 2022
Opdualag [™] (nivolumab/relatlimab-rmbw) [*] Bristol-Myers Squibb	Programmed death receptor-1 blocking antibody/ lymphocyte- activation gene 3 blocking antibody	Treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma	March 22, 2022
Pluvicto [™] (lutetium Lu 177 vipivotide tetraxetan) [*]	Radiopharmaceutical	Treatment of adult patients with prostate-specific membrane antigen - positive metastatic castration-resistant prostate cancer who have	March 27, 2022

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Novartis		been treated with androgen receptor pathway inhibition and taxane-based chemotherapy	
Nasonex® (mometasone furoate monohydrate)± Perrigo	Corticosteroid/ antihistamine	To temporarily relieve symptoms of hay fever or other upper respiratory allergies including nasal congestion, sneezing, runny and itchy nose in patients 2 years of age and older	Late 2022
Ozempic® (semaglutide) 8 mg/3mL (2.68 mg/mL) single-patient-use pen Novo Nordisk	Glucagon-like peptide-1 receptor agonist	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM) and to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with T2DM and established cardiovascular disease	2 nd Quarter 2022
Takhzyro® (lanadelumab-flyo) 300 mg/2 mL prefilled syringe Shire	Kallikrein inhibitor	Prophylaxis to prevent attacks of hereditary angioedema in patients 12 years and older	February 20, 2022
Tlando™ (testosterone undecanoate) Antares Pharma	Androgen	Testosterone replacement therapy in adult males for certain conditions associated with a deficiency or absence of endogenous testosterone	April 4, 2022
Triumeq PD™ (abacavir/dolutegravir/lamivudine) tablets for oral suspension ViiV Healthcare	Integrase strand transfer inhibitor/ nucleoside analogue reverse transcriptase inhibitors	Treatment of HIV-1 infection in adults and in pediatric patients weighing at least 10 kg	April 5, 2022
Xelstrym™ (dextroamphetamine) transdermal patch	Central nervous system stimulant	Treatment of attention deficit hyperactivity disorder in adults and pediatric patients 6 years and older	2 nd half 2022

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Noven Therapeutics			
Ztalmy [®] (ganaxolone) ^{†*} Marinus	GABA(a) receptor modulator	Treatment of seizures associated with cyclin-dependent kinase-like 5 deficiency disorder in patients 2 years of age and older	July 2022

*New molecular entity; † Orphan drug; ±Over-the-counter approval; 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
Apokyn [®] (apomorphine) MDD US Operations	TruPharma/Sage Chemicals ^{†±}	30 mg/3 mL single-patient-use cartridge	Acute, intermittent treatment of hypomobility, "off" episodes in advanced Parkinson's disease	February 24, 2022
Revlimid [®] (lenalidomide) Bristol-Myers Squibb	Teva ^{†±} , Dr. Reddy's [†]	Teva: 5 mg, 10 mg, 15 mg, and 25 mg capsules Dr. Reddy's: 2.5 mg and 20 mg capsules	Multiple myeloma, myelodysplastic syndromes, and mantle cell lymphoma	March 7, 2022 [¥]
Vimpat [®] (lacosamide) Indoco Remedies	Alembic [±] , Amnela [±] , Glenmark [±] , Tris/Indoco [±] , Sun [±] , Camber/Hetero [±]	10 mg/mL oral solution; 50 mg, 100 mg, 150 mg, and 200 mg tablets	Partial-onset seizures; primary generalized tonic-clonic seizures	March 21-22, 2022
Zipsor [®] (diclofenac potassium) Depomed	Aurobindo [†] , Teva [†]	25 mg capsules	Relief of mild to moderate acute pain	March 24, 2022

†A-rated generic manufacturer; ¥Teva's launch is a limited quantity license launch with full launch in January 2026; Dr. Reddy's launch of the 2.5 mg and 20 mg strengths is TBD; ±Granted 180 days of marketing exclusivity; TBD: To be determined

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Indications/Label updates

Drug name manufacturer(s)	Type	Description
Cabenuva™ (cabotegravir/rilpivirine) ViiV Healthcare	New indication	A complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35 kg to replace the current antiretroviral regimen in those who are virologically suppressed on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine
COVID-19 vaccines Pfizer/BioNTech and Moderna	Expanded emergency use authorization	The FDA announced an expanded EUA for Pfizer/BioNTech and Moderna COVID-19 vaccines authorizing use of a second booster dose that may be administered to individuals 50 years of age and older at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine
Fintepla® (fenfluramine) UCB	New indication	Treatment of seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older
Keytruda® (pembrolizumab) Merck	Expanded indication	As a single agent, for the treatment of patients with advanced endometrial carcinoma that is microsatellite instability-high or mismatch repair deficient, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation
Lynparza® (olaparib) AstraZeneca	New indication	Adjuvant treatment of adults with deleterious or suspected deleterious germline BRCA-mutated human epidermal growth factor receptor 2-negative high risk early breast cancer who have been treated with chemotherapy
Opdivo® (nivolumab) Bristol-Myers Squibb	New indication	In combination with platinum-doublet chemotherapy, as neoadjuvant treatment of adults with resectable non-small cell lung cancer
Rinvoq® (upadacitinib) AbbVie	New indication	Treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more tumor necrosis factor blockers

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Drug recalls/Withdrawals/Shortages/Discontinuations

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Accuretic™ (quinapril/hydrochlorothiazide [HCTZ]), quinapril and HCTZ, and quinapril HCl/HCTZ Pfizer	Accuretic: 10 mg/12.5 mg, 20 mg/1.5 mg, and 20 mg/25 mg tablets Quinapril and HCTZ: 20 mg/25 mg tablets Quinapril HCl/HCTZ: 10 mg/1.5 mg and 20 mg/25 mg tablets	Recall	Pfizer announced a consumer-level recall of several lots of Accuretic, quinapril and HCTZ, and quinapril HCl/HCTZ tablets due to the presence of a nitrosamine, N-nitroso-quinapril. Brand and generic Accuretic tablets are indicated for the treatment of hypertension.
Enalapril Golden State Medical Supply	2.5 mg, 5 mg, 10 mg, and 20 mg tablets	Recall	Golden State Medical supply announced a consumer-level recall of several lots of enalapril tablets due to an unknown impurity found in one lot. Enalapril is indicated for the treatment of hypertension, treatment of symptomatic congestive heart failure, and in stable asymptomatic patients with left ventricular dysfunction to decrease the rate of development of overt heart failure and decrease the incidence of hospitalization for heart failure.
Idarubicin injection Teva	5 mg/5 mL injection	Recall	Teva announced a user-level recall of one lot of idarubicin injection because of particulate matter found in one vial. Idarubicin in combination with other approved anti-leukemic drugs is indicated for the treatment of acute myeloid leukemia in adults.
Milk of Magnesia; acetaminophen; and magnesium hydroxide/aluminum hydroxide/simethicone Plastikon Healthcare	Milk of Magnesia 2400 mg/30 mL oral suspension Magnesium hydroxide 1200 mg/ aluminum hydroxide 1200 mg/ simethicone 120 mg per 30 mL oral solution	Recall	Plastikon announced a voluntarily consumer-level recall of some single dose cup products due to the microbial contamination and failure to properly investigate failed microbial testing. Milk of Magnesia is indicated for the occasional relief of constipation. Magnesium hydroxide/aluminum hydroxide/simethicone is indicated for relief of acid indigestion, heartburn, sour stomach, upset stomach due to these symptoms, pressure and bloating commonly referred to as gas. Acetaminophen is indicated for temporarily relief of minor aches and pains due to, minor pain of arthritis, muscular aches, backache,

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	Acetaminophen 650 mg/20.3 mL oral solution		premenstrual and menstrual cramps, the common cold, headache, toothache, and temporarily reduction of fever.
Orphenadrine Sandoz	100 mg extended-release tablets	Recall	Sandoz announced a voluntary consumer-level recall of some lots of orphenadrine extended-release (ER) tablets due to the presence of a nitrosamine impurity, Nitroso-Orphenadrine. Orphenadrine ER tablets are used as an adjunct to rest, physical therapy and other measures for the relief of discomfort associated with acute painful musculoskeletal conditions.
Sodium acetate injection Fresenius Kabi	400 mEq/ 100 mL injection	Recall	Fresenius Kabi announced a user-level recall of seven lots of sodium acetate injection due to the presence of particulate matter found in some vials. Sodium acetate injection is indicated as a source of sodium, for addition to large volume IV fluids to prevent or correct low blood sodium levels in patients with restricted or no oral intake. It is also useful as an additive for preparing specific IV fluid formulas when the needs of the patient cannot be met by standard electrolyte or nutrient solutions.
Symjepi® (epinephrine) Adamis	0.15 mg/0.3 mL and 0.3 mg/0.3 mL pre-filled single dose syringes	Recall	Adamis announced a voluntary consumer-level recall of some lots of Symjepi pre-filled single dose syringes due to the potential clogging of the needle preventing the dispensing of epinephrine.

Key guideline/Literature updates

Topic	Reference
American Gastroenterological Association – Management of Hepatocellular Carcinoma	<u>Gastroenterology</u> . March 2022
American Society of Colon and Rectal Surgeons – Management of Colon Cancer	<u>Diseases of the Colon & Rectum</u> . February 2022
National Institutes of Health – COVID-19 Treatment	<u>COVID-19 Treatment Guidelines</u> . March 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Ampullary Adenocarcinoma - Version 1.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Ampullary Adenocarcinoma</u> . March 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer</u> . March 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas</u> . March 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Dermatofibrosarcoma Protuberans - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Dermatofibrosarcoma Protuberans</u> . March 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers - Version 1.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers</u> . March 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Melanoma: Uveal - Version 1.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Melanoma: Uveal</u> . March 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Merkel Cell Carcinoma - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Merkel Cell Carcinoma</u> . March 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma - Version 5.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma</u> .

Topic	Reference
	March 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer - Version 3.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</u> March 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Aggressive Mature B-Cell Lymphomas - Version 3.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Aggressive Mature B-Cell Lymphomas.</u> March 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma - Version 1.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma.</u> March 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma - Version 1.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma.</u> March 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic.</u> March 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Antiemesis - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Antiemesis.</u> March 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer-Associated Venous Thromboembolic Disease - Version 1.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Cancer-Associated Venous Thromboembolic Disease.</u> March 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Palliative Care - Version 1.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Palliative Care.</u> March 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Survivorship - Version 1.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Survivorship.</u> March 2022

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Older Adult Oncology - Version 1.2022	<u><i>NCCN Clinical Practice Guidelines in Oncology: Older Adult Oncology.</i></u> March 2022



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