

RxHighlights

October 2022

New drugs

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Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Furoscix [®] (furosemide) scPharmaceuticals	Diuretic	Treatment of congestion due to fluid overload in adult patients with New York Heart Association Class II and Class III chronic heart failure	October 14, 2022
Imjudo [®] (tremelimumab-actl) ^{†*} AstraZeneca	Cytotoxic T lymphocyte- associated antigen 4 inhibitor	Treatment of adult patients with unresectable hepatocellular carcinoma	October 26, 2022
Tecvayli [™] (teclistamab-cqyv) ^{†*} Janssen	Bispecific BCMA- directed CD3 T-cell engager	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	October 28, 2022

*New molecular entity; †Orphan drug

New generics

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Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Cetrotide [®] (cetorelix) EMD Serono	Akorn ^{†*}	0.25 mg powder for injection	Inhibition of premature luteinizing hormone surges in women undergoing controlled ovarian stimulation	October 24, 2022
Daliresp [®] (roflumilast) AstraZeneca	Micro Labs [†] , Viatris [†] , Zydus [†] , Solco [†] ,	Novadoz: 250 mcg;	Treatment to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbations in patients with severe	October 20, 2022

Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
	Novadoz [†] , Strides [†] , and Camber [†]	Micro Labs, Viatris, Zydus, Solco, Novadoz, Strides, and Camber: 500 mcg tablets	COPD associated with chronic bronchitis and a history of exacerbations	

[†]A-rated generic manufacturer; [±]Granted 180 days marketing exclusivity

New authorized brand alternatives

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Drug name manufacturer(s)	Authorized brand alternative manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Divigel [®] (estradiol) Vertical	Trigen	0.1% transdermal gel	Treatment of moderate to severe vasomotor symptoms due to menopause	October 4, 2022

Indications/Label updates

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Drug name manufacturer(s)	Type	Description
Boostrix (tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed) GSK	New indication	Immunization during the third trimester of pregnancy to prevent pertussis in infants younger than 2 months of age
Cotellic [®] (cobimetinib) Genentech	New orphan indication	As a single agent, for the treatment of adults with histiocytic neoplasms

Drug name manufacturer(s)	Type	Description
COVID-19 vaccines – bivalent booster (original and omicron BA.4/BA.5) Moderna and Pfizer/BioNTech	Updated emergency use authorizations (EUA) and CDC approval	Moderna COVID-19 vaccine, bivalent is authorized as a booster dose in individuals 6 years of age and older. Pfizer/BioNTech COVID-19 vaccine, bivalent is authorized as a booster dose in individuals 5 years of age and older. The previously authorized monovalent mRNA COVID-19 vaccine, Comirnaty® is no longer authorized as a booster dose for individuals 5 to 11 years of age.
COVID-19 vaccine, adjuvanted Novavax	Booster dose EUA	To provide a first booster dose to individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Novavax COVID-19 vaccine because they would otherwise not receive a booster dose of a COVID-19 vaccine
Lyumjev® (insulin lispro-aabc) Eli Lilly	Expanded indication	To improve glycemic control in adult and pediatric patients with diabetes mellitus
Oxlumo™ (lumasiran) Alnylam Pharmaceuticals	Expanded indication	Treatment of primary hyperoxaluria type 1 to lower urinary and plasma oxalate levels in pediatric and adult patients
Rinvoq® (upadacitinib) AbbVie	New indication	Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to tumor necrosis factor blocker therapy
Vemlidy® (tenofovir alafenamide) Gilead	Expanded indication	Treatment of chronic hepatitis B virus infection in adults and pediatric patients 12 years of age and older with compensated liver disease

Drug recalls/Withdrawals/Shortages/Discontinuations

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Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Amphetamine mixed salts Various manufacturers	5 mg, 7.5 mg, 10 mg, 12 mg, 12.5 mg, 15 mg, 20 mg, 30 mg immediate release tablets	Shortage	The FDA announced a shortage of the immediate release formulation of amphetamine mixed salts. Amphetamine mixed salts are approved for the treatment of attention deficit hyperactivity disorder and narcolepsy.
Menopur® (menotropins for injection) Ferring	Powder for injection containing 75 IU FSH and 75 IU of LH activity, supplied as lyophilized powder or pellet in sterile vials with diluent vials and Q•Cap® vial adapters	Temporary discontinuation	Ferring announced the temporary suspension of all shipments of Menopur because of changes made by a third-party supplier in the manufacturing process. The suspension is not due to safety or efficacy concerns. Ferring is not aware of any evidence indicating that the changes in manufacturing process pose any risks to patients and there is no estimated time frame as to when they will resume shipment. Menopur is indicated for the development of multiple follicles and pregnancy in ovulatory women as part of an assisted reproductive technology cycle.
Quinapril/hydrochlorothiazide Aurobindo	20 mg/12.5 mg tablets	Recall	The FDA announced a consumer level recall of two lots of Aurobindo's quinapril/hydrochlorothiazide 20 mg/12.5 mg tablets due to the presence of nitrosamine drug substance related impurity, N-Nitroso-Quinapril, above the proposed interim limit.
Ready-to-feed liquid products Abbott	Various brands of 2 fl. oz./59 mL ready-to-feed liquid products	Recall	Abbott announced a voluntary, consumer-level recall of certain lots of ready-to-feed liquid products for infants and children, including the brands Similac® Pro-Total Comfort™, Similac® 360 Total Care®, Similac 360 Total Care Sensitive, Similac® Special Care® 24, Similac Stage 1, Similac® NeoSure®, Similac Water (Sterilized) and Pedialyte Electrolyte Solution because a small percentage of bottles (less than 1%) have caps that may have not sealed completely which could result in spoilage.
Sodium bicarbonate Exela	8.4 % injection	Recall	Exela Pharma Sciences announced a voluntary consumer-level recall of forty-nine lots of sodium bicarbonate 8.4% injection because the product poses a potential safety concern with vial breakage and

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
			<p>flying glass when pressurized while preparing the product for administration.</p> <p>Sodium bicarbonate injection is indicated in the treatment of metabolic acidosis.</p>

Key guideline/Literature updates

Topic	Reference
American Gastroenterological Association – Management of adults with obesity	<u>Gastroenterology</u> . October 2022
National Institutes of Health – COVID-19 Treatment	<u>COVID-19 Treatment Guidelines</u> . October 2022
World Professional Association for Transgender Health - Health of Transgender and Gender-Diverse People Clinical Practice Guidelines	<u>International Journal of Transgender Health</u> . September 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer</u> . October 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers - Version 3.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers</u> . October 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Malignant Peritoneal Mesothelioma - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Malignant Peritoneal Mesothelioma</u> . October 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Malignant Pleural Mesothelioma - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Malignant Pleural Mesothelioma</u> . October 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma - Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma</u> .

Topic	Reference
	October 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes.</u> October 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Aggressive Mature B-Cell Lymphomas - Version 3.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Aggressive Mature B-Cell Lymphomas.</u> October 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Central Nervous System Cancers - Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Central Nervous System Cancers.</u> October 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer - Version 3.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer.</u> October 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma.</u> October 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer - Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer.</u> October 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Systemic Mastocytosis - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Systemic Mastocytosis.</u> October 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thyroid Carcinoma - Version 3.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma.</u> October 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Wilms Tumor (Nephroblastoma) - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Wilms Tumor (Nephroblastoma).</u> October 2022

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer Risk Reduction - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Risk Reduction.</u> October 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Lung Cancer Screening - Version 1.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Lung Cancer Screening.</u> October 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prevention and Treatment of Cancer-Related Infections - Version 3.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Prevention and Treatment of Cancer-Related Infections.</u> October 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adolescent and Young Adult (AYA) Oncology - Version 2.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Adolescent and Young Adult (AYA) Oncology.</u> October 2022

