

RxHighlights

April 2022

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New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Caplyta [®] (lumateperone) 10.5 mg and 21 mg capsules Intra-Cellular Therapies	Antipsychotic	Treatment of schizophrenia in adults as well as bipolar depression in adults (as monotherapy and as adjunctive therapy with lithium or valproate)	Mid-2022
Camzyos [™] (mavacamten) ^{†*} Bristol Myers Squibb	Cardiac myosin allosteric modulator	Treatment of adults with symptomatic New York Heart Association class II-III obstructive hypertrophic cardiomyopathy to improve functional capacity and symptoms	May 2, 2022
Epsolay [®] (benzoyl peroxide) 5% cream Sol-Gel Technologies	Benzoyl peroxide	Treatment of inflammatory lesions of rosacea in adults	TBD
Igalmi [™] (dexmedetomidine) BioXcel Therapeutics	Alpha-2 adrenergic receptor agonist	Acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults	Second quarter of 2022
Cuvrior [™] (trientine tetrahydrochloride) [†] Orphalan	Copper chelator	Treatment of adult patients with stable Wilson's disease who are de-coppered and tolerant to penicillamine	TBD
Vijoice [®] (alpelisib) [†] Novartis	Kinase inhibitor	Treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum who require systemic therapy	April 10, 2022
Vivjoa [™] (oteseconazole) [*] Mycovia	Lanosterol demethylase (CYP51) inhibitor	To reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are not of reproductive potential	Second quarter of 2022

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

New biosimilars

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Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Alymsys [®] (bevacizumab-maly) Amneal	Vascular endothelial growth factor inhibitor	Metastatic colorectal cancer; first-line non-squamous non-small cell lung cancer; recurrent glioblastoma; metastatic renal cell carcinoma; persistent, recurrent, or metastatic cervical cancer, and epithelial ovarian, fallopian tube, or primary peritoneal cancer	TBD

New generics

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Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Bidil [®] (isosorbide dinitrate/hydralazine) Arbor	Ingenus/Riconpharma ^{±†}	20 mg/37.5 mg tablets	Heart failure	April 12, 2022
Vimpat [®] (lacosamide) UCB	Indoco Remedies [†] , Sagent [†]	200 mg/ 2 mL injection	Partial-onset seizures, and as adjunctive therapy for primary generalized tonic-clonic seizures	April 8, 2022

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

New authorized brand alternatives

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Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Abraxane[®] (paclitaxel, protein-bound) Abraxis BioScience	Apotex, TWi	100 mg/20 mL injection	Metastatic breast cancer, non-small cell lung cancer and adenocarcinoma of the pancreas	April 12, 2022
Bidil[®] (isosorbide dinitrate/hydralazine) Arbor	Wilshire	20 mg/37.5 mg tablets	Heart failure	April 14, 2022

Indications/Label updates

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Drug name manufacturer(s)	Type	Description
Ninlaro[®] (ixazomib) Takeda	Updated labeling	The FDA added a limitation of use for Ninlaro, stating that it is not recommended for use in the maintenance setting or in newly diagnosed multiple myeloma in combination with lenalidomide and dexamethasone outside of controlled clinical trials
Qelbree[®] (viloxazine) Supernus	Expanded indication	Treatment of attention-deficit hyperactivity disorder in adults and pediatric patients 6 years and older
Rinvoq[®] (upadacitinib) AbbVie	New indication	Treatment of adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more tumor necrosis factor blockers
Sotrovimab GlaxoSmithKline	Emergency use authorization revision	The FDA announced that sotrovimab is no longer authorized to treat COVID-19 in any U.S. region due to increases in the proportion of COVID-19 cases caused by the Omicron BA.2 sub-variant

Drug name manufacturer(s)	Type	Description
Ultomiris [®] (ravulizumab-cwvz) AstraZeneca	New orphan indication	Treatment of adults with generalized myasthenia gravis who are anti-acetylcholine receptor antibody-positive
Veklury [®] (remdesivir) Gilead	Expanded indication	Treatment of COVID-19 in pediatric patients (≥ 28 days old and weighing ≥ 3 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, who are hospitalized, or not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death
Yescarta [®] (axicabtagene ciloleucel) Gilead	Expanded indication	Treatment of adults with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy
Zerbaxa [®] (ceftolozane/tazobactam) Merck	Expanded indication	Treatment of the following infections caused by designated susceptible microorganisms in adult and pediatric patients (birth to < 18 years old): complicated intra-abdominal infections (used in combination with metronidazole), and complicated urinary tract infections, including pyelonephritis

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Drug safety news / Drug updates

Drug name manufacturer(s)	Description
Aduhelm™ (aducanumab) Biogen	<p>The Centers for Medicare and Medicaid Services announced the final National Coverage Determination (NCD) policy for Medicare coverage of Aduhelm. The NCD policy states that Aduhelm will be provided under Medicare coverage when used as part of a CMS approved clinical trial.</p>
AMX0035 (sodium phenylbutyrate/taurursodiol) Amylyx Pharmaceuticals, Inc	<p>The FDA Advisory Committee met to discuss the available data supporting the AMX0035, a pipeline drug seeking approval for the treatment of amyotrophic lateral sclerosis, also commonly known as Lou Gehrig's disease. The Advisory Committee was asked if the data from the phase 2 trial and the open label extension was sufficient to determine that the drug is effective for the treatment of ALS. After much debate and discussion, the members voted 6-4 against AMX0035.</p>
COVID-19 Vaccines	<p>The FDA convened a Vaccine and Biologic Products Advisory Committee to discuss considerations for use of COVID-19 vaccine booster doses and the process for COVID-19 vaccine strain selection to address current and emerging variants.</p> <p>The Center for Disease Control and Prevention's Advisory Committee for Immunization Practices Committee met to discuss COVID-19 vaccine policy and updates on the effectiveness and safety of booster doses. The ACIP COVID-19 vaccine work group supports the recent CDC recommendation that immunocompromised individuals ages 12 and over and people over the age of 50 may receive a second COVID-19 mRNA vaccine booster dose.</p>

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Drug recalls/Withdrawals/Shortages/Discontinuations

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Accupril™ (quinapril) Pfizer	10 mg, 20 mg, and 40 mg tablets	Recall	<p>Pfizer announced a consumer-level recall of several lots of Accupril due to the presence of a nitrosamine, N-nitroso-quinapril, observed in recent testing above certain levels.</p> <p>Accupril is indicated for the treatment of hypertension and for the management of heart failure as adjunctive therapy when added to conventional therapy including diuretics and/or digitalis.</p>
Arformoterol Glenmark	15 mcg/ 2 mL inhalation solution	Recall	<p>Glenmark announced a consumer-level recall of several lots of arformoterol inhalation solution due to a lack of assurance of product sterility discovered after a review of the manufacturing facility's microbiology laboratory controls and processes.</p> <p>Arformoterol is indicated for the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema.</p>
Chlorzoxazone Glenmark	375 mg, 750 mg tablets	Recall	<p>Glenmark announced a consumer-level recall of some lots of chlorzoxazone tablets due to gaps in the microbiology quality control system.</p> <p>Chlorzoxazone is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions.</p>
Insulin glargine (insulin glargine-yfgn) Mylan/Viatris	100 units/mL injection	Recall	<p>Mylan/Viatris announced a consumer-level recall of one lot of insulin glargine injection due to the potential for the label to be missing on some vials.</p> <p>Insulin glargine-yfgn is indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.</p>
Naproxen Glenmark	275 mg tablets	Recall	<p>Glenmark announced a consumer-level recall of two lots of naproxen tablets due to gaps in the microbiology quality control system.</p> <p>Naproxen is indicated for the relief of the signs and symptoms of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis,</p>

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
			polyarticular juvenile idiopathic arthritis, tendonitis, bursitis, acute gout; and for the management of pain and primary dysmenorrhea.
Similac[®], Alimentum[®], EleCare[®] infant formula Abbott	Various package sizes	Recall	Abbott announced an expansion of the consumer-level recall of Similac, Alimentum and EleCare infant formulas after four consumer complaints related to Cronobacter sakazakii or Salmonella Newport in infants who had consumed powder infant formula manufactured at one of Abbott's facilities. Additional lots are being recalled. This is an expansion to the recall that was first announced February 17, 2022.
Ukoniq[™] (umbralisib) TG Therapeutics	200 mg tablets	Voluntary withdrawal	TG Therapeutics announced the voluntary withdrawal of Ukoniq from sale for the approved indications of treatment of adults with marginal zone lymphoma who have received at least one prior anti-CD20-based regimen, and treatment of adults with follicular lymphoma who have received at least three prior systemic therapies. The withdrawal was based on a clinical study that showed an increasing imbalance in favor of the control arm Gazyva [®] (obinutuzumab) vs. the combination of ublituximab and Ukoniq.
Zonisamide Glenmark	25 mg, 50 mg, and 100 mg capsules	Recall	Glenmark announced a consumer-level recall of several lots of zonisamide capsules due to gaps in the microbiology quality control system or due to lack of stability data. Zonisamide is indicated as adjunctive therapy in the treatment of partial seizures in adults with epilepsy.

Key guideline/Literature updates

Topic	Reference
World Health Organization – Management of Tuberculosis in Children and Adolescents	<u>WHO Operational Handbook on tuberculosis: Module 5: Management of Tuberculosis in Children and Adolescents</u> . March 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas - Version 3.2022	<u>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas</u> . April 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Head and Neck Cancers - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers</u> . April 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous - Version 3.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous</u> . April 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes - Version 1.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes</u> . April 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms</u> . April 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Aggressive Mature B-Cell Lymphomas - Version 1.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Aggressive Mature B-Cell Lymphomas</u> . April 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Hodgkin Lymphoma - Version 1.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Hodgkin Lymphoma</u> . April 2022

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Systemic Mastocytosis - Version 1.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Systemic Mastocytosis.</u> April 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Wilms Tumor (Nephroblastoma) - Version 1.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Wilms Tumor (Nephroblastoma).</u> April 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal.</u> April 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Smoking Cessation - Version 1.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Smoking Cessation.</u> April 2022



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