MC-Rx

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Insights on the Drugs Pipeline

Exploring the changes in the drugs market.

April 2022

MC-Rx is dedicated to improved drug therapy vigilance, continuity of care, patient safety and effective formulary management. This edition is developed by our clinical team, which is comprised of registered clinical pharmacists, to provide you with continuous evaluation and insights of the drugs market and its impact as it evolves.

Here you will find

Drug pipeline

FDA drug approvals

New indications

Patent expirations

Generic approvals

FDA safety updates/ withdrawals/ recalls

Drug shortages/ discontinuations

COVID-19 Emergency Use Authorization (EUA) Update

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Date of first EUA issuance	Treatment	Authorized use	Clinical Studies
02/11/2022	Bebtelovimab	Bebtelovimab is authorized for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate. Bebtelovimab is currently authorized in all U.S. regions until further notice by the Agency.	• The data supporting this EUA for treatment of mild-to-moderate COVID-19 are primarily based on analyses of data from the Phase 2 portion of the BLAZE-4 trial (NCT04634409) that enrolled both low risk and high risk subjects (treatment arms 9-14). This trial evaluated the clinical efficacy data from subjects receiving 175 mg bebtelovimab alone and together with 700 mg bamlanivimab and 1,400 mg of etesevimab. • BLAZE-4 is a Phase 1/2, randomized, single-dose clinical trial evaluating treatment of subjects with mild-to-moderate COVID-19 (subjects with COVID-19 symptoms who are not hospitalized). Efficacy of bebtelovimab, alone and together with bamlanivimab and etesevimab, was evaluated in low risk adults (i.e., those not at high-risk to progress to severe COVID-19) in a randomized part of the trial which included a placebo control arm (treatment arms 9-11). Another cohort of high risk subject was enrolled with no randomization (treatment arm 14). The trial enrolled subjects who were not hospitalized and had 1 or more COVID19 symptoms that were at least mild in severity.

COVID-19 Vaccines Updates

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Date	Update
03/21/2022	**Coronavirus (COVID-19) Update: FDA to Hold Advisory Committee Meeting on COVID-19 Vaccines to Discuss Future Boosters** On Wed., April 6, FDA will hold a virtual meeting of its Vaccines and Related Biological Products Advisory Committee to discuss considerations for future COVID-19 vaccine booster doses and the strain selection process to address current and emerging variants during the Fall season 2022.
02/11/2022	**FDA Postpones Advisory Committee Meeting to Discuss Request for Authorization of Pfizer-BioNTech COVID-19 Vaccine on Children 6 Months Through 4 Years of Age:** The FDA has been notified by Pfizer that new data have recently emerged regarding its emergency use authorization request for the use of the Pfizer-BioNTech COVID-19 Vaccine in children 6 months through 4 years of age. Based on the agency's preliminary assessment, and to allow more time to evaluate additional data, we believe additional information regarding the ongoing evaluation of a third dose should be considered as part of our decision-making for potential authorization.
01/31/2022	**FDA Takes Key Action By Approving Second COVID-19 Vaccine:** The FDA approved a second COVID-19 vaccine. The vaccine has been known as the Moderna COVID-19 Vaccine; the approved vaccine will be marketed as Spikevax for the prevention of COVID-19 in individuals 18 years of age and older.
01/07/2022	**FDA Shortens Interval for Booster Dose of Moderna COVID-19 Vaccine to Five Months:** Today, the FDA amended the emergency use authorization (EUA) for the Moderna COVID-19 Vaccine to shorten the time between the completion of a primary series of the vaccine and a booster dose to at least five months for individuals 18 years of age and older.

COVID-19 Vaccine Booster Shots - CDC Recommendations

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Vaccine that was administered:	Who should get a booster?	When to get a booster?	Which booster can you get?
Pfizer-BioNTech	Everyone 12 years and older	At least 5 months after completing your primary COVID-19 vaccination series	Teens 12-17 years old can get a Pfizer-BioNTech COVID-19 vaccine booster Adults 18 years and older: Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) are preferred in most situations
Moderna	Adults 18 years and older	At least 5 months after completing your primary COVID-19 vaccination series	Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) are preferred
Johnson & Johnson's Janssen	Adults 18 years and older	At least 2 months after completing your primary COVID-19 vaccination	Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) are preferred

References:

- Emergency Use Authorization: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs
- FDA COVID-19 Vaccine News and Updates: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines
- COVID-19 Vaccine Booster Shots: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html

Specialty Pipeline

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

There is a growing trend of specialty drugs in the market. Therapeutic areas where the specialty drug pipeline could yield new approvals in the coming years include treatments for dermatologic conditions, hemophilia, genetic disorders, among others.

Pipeline Drug	Current Status	Anticipated Approval	Indication
Adagrasib (Mirati Therapeutics)	Phase 2	2022	KRAS G12C specific inhibitor for the treatment of KRAS G12C- mutated locally advanced or metastatic non-small cell lung cancer (NSCLC); oral *Breakthrough Therapy*
Arimoclomol (Miplyffa - Orphazyme)	Complete Response	2022	Molecular chaperone activator that stimulates the normal cellular protein repair pathway for the treatment of NiemannPick Disease Type C (NPC); oral *Breakthrough Therapy* *Orphan Drug*
Bardoxolone methyl (Reata Pharmaceuticals)	NDA Filed	02/25/2022	Antioxidant inflammation inhibitor that acts on Nrf2 for the treatment of chronic kidney disease caused by Alport Syndrome; oral *Orphan Drug*
Betibeglogene autotemcel (Zynteglo Bluebird Bio)	BLA Filed	05/21/2022	Gene therapy for the treatment of ß-globin gene therapy for the treatment of transfusion-dependent ß thalassemia; IV infusion *Breakthrough Therapy* *Orphan Drug*
Bimekizumab (UCB)	BLA Filed	11/15/2021	Monoclonal antibody that blocks the effects of IL-17A and IL-17F for the treatment of moderate-to-severe plaque psoriasis; SC injection
Cipaglucosidase alfa (Amicus Therapeutics)	BLA Filed	05/29/2022	Recombinant human acid α-glucosidase (rhGAA) enzyme replacement therapy/chaperone therapy for the treatment of late-onset Pompe disease; IV infusion *Breakthrough Therapy* *Orphan Drug*
Deucravacitinib (Bristol Myers Squibb)	NDA Filed	09/10/2022	Tyrosine kinase 2 (TYK2) inhibitor for use in patients with moderate to severe plaque psoriasis; oral therapy

Specialty Pipeline

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Pipeline Drug	Current Status	Anticipated Approval	Indication
Eladocagene exuparvovec (PTC Therapeutics)	Phase 3	2022	Recombinant, adeno-associated virus, containing the human cDNA encoding the AADC enzyme for the treatment of AADC deficiency; intracerebral infusion *Orphan Drug*
Futibatinib (Taiho Oncology)	Phase 3	2022	Fibroblast growth factor (FGFR) 1-4 inhibitor for the treatment of patients with previously treated locally advanced or metastatic cholangiocarcinoma harboring FGFR2 gene rearrangements, including gene fusions; oral *Breakthrough Therapy* *Orphan Drug*
lecanemab (Eisai/ Biogen)	Rolling Submission	2022	Humanized IgG1 monoclonal antibody that binds selectively to large, soluble Aß protofibrils and is thought to lead to their clearance or neutralize their toxicity for treatment of Alzheimer's Disease; IV infusion *Breakthrough Therapy*
Obeticholic acid (Intercept Pharmaceuticals)	Complete Response	2022	Farnesoid X receptor (FXR) agonist for the treatment of nonalcoholic steatohepatitis (NASH); oral Breakthrough Therapy Orphan Drug
Pacritinib (CTI BioPharma)	NDA Filed	2022	Janus kinase 2 (JAK-2) and interleukin 1 Receptor Associated Kinase 1 (IRAK1) inhibitor for the treatment of chronic idiopathic myelofibrosis with severe thrombocytopenia (platelet counts less than 50 x 109/L); oral Orphan Drug
Pegunigalsidase alfa (Protalix BioTherapeutics)	Complete Response	2022	Plant cell-expressed, recombinant alpha-galactosidase-A enzyme for the treatment of Fabry disease; IV infusion (monthly) *Breakthrough Therapy* *Orphan Drug*

Specialty Pipeline

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Pipeline Drug	Current Status	Anticipated Approval	Indication
Spesolimab (Boehringer Ingelheim)	BLA Filed	06/15/2022	Humanized monoclonal antibody that blocks activation of the interleukin-36 receptor for the treatment of generalized pustular psoriasis (GPP) flares; IV/SC *Breakthrough Therapy* *Orphan Drug*
Sutimlimab (Sanofi)	BLA Filed	02/05/2022	Anti-C1s antibody for the treatment of primary cold agglutinin disease (CAD); IV infusion *Breakthrough Therapy* *Orphan Drug*
Teclistamab (Janssen)	BLA Filed	08/29/2022	BCMA/CD3 bispecific antibody for the treatment of relapsed or refractory multiple myeloma; SC *Breakthrough Therapy* *Orphan Drug*
Teplizumab (Provention Bio)	Complete Response	2022	Humanized monoclonal antibody engineered to alter the function of the T lymphocytes that mediate the destruction of the insulin-producing beta cells of the islets of the pancreas to delay or prevent the onset of type 1 diabetes in at-risk individuals; IV *Breakthrough Therapy*
Valoctocogene roxaparvovec (Roctavian - BioMarin Pharmaceuticals)	Complete Response	2022	Adenovirus-associated virus vector-mediated the transfer of Human Factor VIII gene in patients with severe hemophilia A; IV Infusion *Breakthrough Therapy* *Orphan Drug*
Vutrisiran (Alnylam Pharmaceuticals)	NDA Filed	04/14/2022	Therapeutic targeting transthyretin (TTR) for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis in adults; SC *Orphan Drug*

Biosimilar Pipeline

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Below is a list of biosimilars that are currently under FDA review. Approval of a biosimilar does not imply availability and allocation in the market. Additional patent, exclusivities, settlement agreements, etc. may result in a delay in launch of a biosimilar.

Pipeline Biosimilar	Manufacturer	Reference Biologic	Posible FDA Approval Date	Potential Launch Date
Bevacizumab (Almysys)	Amneal	Avastin (bevacizumab)	4/17/2022	TBD (Pending FDA Approval)
Pegfilgrastim (Lupifil-P)	Lupin	Neulasta (pegfilgrastim)	4/2/2022	TBD (Pending FDA Approval)
Ranibizumab-ranq (Cimerli)	Bioeq/Coherus	Lucentis (ranibizumab)	8/5/2022	TBD (Pending FDA Approval)
Adalimumab-bwwd (Hadlima)	Biogen/Samsung Bioepis	Humira (adalimumab)	8/31/2022	Settlement: July 1, 2023
Trastuzumab biosimilar	EirGenix/Sandoz	Herceptin (trastuzumab)	10/20/2022	TBD (Pending FDA Approval)
Aflibercept biosimilar	Momenta/Viatris	Eylea (aflibercept)	2022	TBD
Bevacizumab biosimilar (Abevmy)	Viatris/Biocon	Avastin (bevacizumab)	2022	TBD (Pending FDA Approval)
Bevacizumab biosimilar (Aybintio)	Samsung Bioepis/ Merck	Avastin (bevacizumab)	2022	TBD (Pending FDA Approval)
Adalimumab biosimilar	Cipla/Alvotech	Humira (adalimumab)	2022	Ongoing Litigation: late 2022
Pegfilgrastim biosimilar (Stimufend)	Fresenius Kabi	Neulasta (pegfilgrastim)	2022	TBD (Pending FDA Approval)
Filgrastim biosimilar	Adello Biologic	Neupogen (filgrastim)	2022	TBD (Pending FDA Approval)
Pegfilgrastim biosimilar	Adello Biologic	Neulasta (pegfilgrastim)	2022	TBD (Pending FDA Approval)
Bevacizumab biosimilar	Biothera	Avastin (bevacizumab)	2022	TBD (Pending FDA Approval
Filgrastim biosimilar	Tanvex BioPharma	Neupogen (filgrastim)	2022	TBD (Pending FDA Approval)
Trastuzumab biosimilar	Tanvex BioPharma	Herceptin (trastuzumab)	2022	TBD (Pending FDA Approval
Insulin aspart biosimilar (Kixelle)	Voatros/biocon	Novolog (insulin aspart)	2022	TBD (Pending FDA Approval)

New Drug Formulations

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Drug Name	Information
Amlodipine (Norliqva)	**Dose:** Oral solution: 1 mg/mL. **Indications:** • Hypertension - NORLIQVA is indicated for the treatment of hypertension in adults and children 6 years of age and older, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. • Coronary Artery Disease: o Chronic Stable Angina o Vasospastic Angina (Prinzmetal's or Variant Angina) o Angiographically Documented Coronary Artery Disease in patients without heart failure or an ejection fraction. **Comparables:** Amlodipine tab (Norvasc), Amlodipine oral suspension (Katerzia) **Guidelines:** • 2020 International Society of Hypertension Global Hypertension Practice Guidelines: https://www.ahajournals.org/doi/epdf/10.1161/HYPERTENSIONAHA.120.15026 • 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines: https://www.jacc.org/doi/pdf/10.1016/j.jacc.2017.11.006 • Stable Coronary Artery Disease: Treatment (American Academy of Family Physicians 2018) - https://www.aafp.org/afp/2018/0315/afp20180315p376.pdf
Ranolazine (Aspruzyo Sprinkle)	**Dose:** Extended-release granules: 500 and 1000 mg **Indication:** For the treatment of chronic angina. **Comparables:** Ranolazine tablets (Ranexa) **Guidelines:** Stable Coronary Artery Disease: Treatment (American Academy of Family Physicians 2018) - https://www.aafp.org/afp/2018/0315/afp20180315p376.pdf
Donepezil transdermal system (Adlarity)	**Dose:** Transdermal System: 5 mg/day and 10 mg/day **Indication:** Is an acetylcholinesterase inhibitor indicated for the treatment of mild, moderate, and severe dementia of the Alzheimer's type. **Comparables:** Donepezil hydrochloride tablets (Aricept), Donepezil hydrochloride orally disintegrating tablets (Aricept ODT) **Guidelines:** • Alzheimer Disease: Pharmacologic and Nonpharmacologic Therapies for Cognitive and Functional Symptoms https://www.aafp.org/afp/2017/0615/p771.html • Practice Guideline For The Treatment Of Patients With Alzheimer's Disease And Other Dementias – American Psychiatric Association (2014) https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/alzheimerwatch.pdf

New Drug Indications

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Drug Name	Information
Doravirine (Pifeltro)	**Dose:** Tablets: 100 mg doravirine **New Indication:** Indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg: with no prior antiretroviral treatment history, OR to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to doravirine. **Guidelines:** Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection - HHS Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV (Reviewed Dec. 30, 2021) https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/PedARV_GL.pdf
Doravirine/ lamivudine/ tenofovir disoproxil fumarate (Delstrigo)	**Dose:** Tablets: 100 mg of doravirine, 300 mg of lamivudine, and 300 mg of tenofovir disoproxil fumarate. **New Indication:** Indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg: • with no antiretroviral treatment history, OR • to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of Delstrigo. **Guidelines:** Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection - HHS Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV (Reviewed Dec. 30, 2021) https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/PedARV_GL.pdf
Secnidazole (Solosec)	**Dose:** Oral granules: 2 g secnidazole, in a unit-of-use child-resistant foil packet.weight **New Indication:** • Treatment of bacterial vaginosis in female patients 12 years of age and older. • Treatment of trichomoniasis in patients 12 years of age and older. **Guidelines:** • Bacterial Vaginosis – STI Treatment Guidelines (CDC, Last Review: July 22, 2021) https://www.cdc.gov/std/treatment-guidelines/bv.htm • Trichomoniasis – STI Treatment Guidelines (CDC, Last Review: July 22, 2021) https://www.cdc.gov/std/treatment-guidelines/trichomoniasis.htm

New Drug Indications

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Drug Name	Information
Dapagliflozin and Metformin Hydrochloride (Xigduo XR)	**Dose:** 2.5 mg dapagliflozin/1000 mg metformin HCl extended-release; 5 mg dapagliflozin/500 mg metformin HCl extended-release **New Indication:** Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Dapagliflozin is indicated to reduce: • The risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors. • The risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction. **Comparables:** Synjardy/Synjardy XR, Invokamet/ Invokamet XR, Segluromet Guidelines: Standards of Medical Care in Diabetes – American Diabetes Association (2022) https://diabetesjournals.org/care/issue/45/Supplement_1
Empagliflozin (Jardiance)	**Dose:** Tablets: 10 mg, 25 mg **Indication:** To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure. **Guidelines:** 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction https://www.jacc.org/doi/pdf/10.1016/j.jacc.2020.11.022
Upadacitinib (Rinvoq)	**Dose:** Extended-release tablets: 15 mg, 30 mg, and 45 mg (new) **Indication:** Adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers. **Comparables:** Tofacitinib (Xeljanz), Ozanimod (Zeposia) **Guidelines:** AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis (2020) – https://www.gastrojournal.org/action/showPdf?pii=S0016-5085%2820%2930018-4
Nivolumab (Opdivo)	**Dose:** Injection: 40 mg/4 mL, 100 mg/10 mL, 120 mg/12 mL, and 240 mg/24 mLsolution in a single-dose vial. **Indication:** Non-Small Cell Lung Cancer (NSCLC) in Adult patients with resectable (tumors ≥4 cm or node positive) non-small cell lung cancer in the neoadjuvant setting, in combination with platinum-doublet chemotherapy. **Guidelines:** NCCN Guidelines – Non-Small Cell Lung Cancer (Version 3.2022 – March 16, 2022)
Olaparib (Lynparza)	**Dose:** Tablets: 150 mg, 100 mg **Indication:** Breast cancer: for the adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCAm human epidermal growth factor receptor 2 (HER2)-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant hemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. **Guidelines:** NCCN Guidelines – Breast Cancer (Version 2.2022 – December 20, 2021)

In Market Brand

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Drug Name	Information
COVID-19 Vaccine, mRNA (Spikevax)	**Dose:** Suspension for injection. A single dose is 0.5 mL. **Indication:** For active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. **Comparables:** COVID-19 Vaccine, mRNA (Comirnaty) **Guidelines:** • Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States (CDC; Last reviewed on February 17, 2022) - https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html • COVID-19 ACIP Vaccine Recommendations (CDC; Last reviewed: February 3, 2022) - https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html
Mitapivat (Pyrukynd)	**Dose:** Tablets: 5 mg, 20 mg, and 50 mg. **Indication:** for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency. **Comparables:** First FDA-approved medicine for this rare and debilitating blood disorder. Before the approval, the only options for treatment were red blood cell transfusions or spleen removal surgery. **Guidelines:** Pyruvate Kinase Deficiency - National Organization for Rare Disorders https://rarediseases.org/rare-diseases/pyruvate-kinase-deficiency/
Tebentafusp-tebn (Kimmtrak)	**Dose:** Injection: 100 mcg/0.5 mL solution in a single-dose vial **Indication:** Is a bispecific gp100 peptide-HLA-directed CD3 T cell engager indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma. **Comparables:** First FDA approval for a rare cancer of the eye that has spread elsewhere or grown too large to be surgically removed. Uveal melanoma is version of the aggressive skin cancer that appears in eye tissue. Less than 2,500 cases are diagnosed each year worldwide, with an estimated 400 eligible patients in the U.S. **Guidelines:** NCCN Guidelines – Melanoma: Uveal (Version 2.2021 – June 25,2021)
Faricimab-svoa (Vabysmo)	**Dose:** Injection: 120 mg/mL solution in a single-dose vial **Indication:** Is a vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) inhibitor indicated for the treatment of patients with: Neovascular (Wet) Age-Related Macular Degeneration (nAMD), Diabetic Macular Edema (DME). **Comparables:** Lucentis, Eylea, Avastin (off label). **Guidelines:** • American Academy of Ophthalmology, Retina/Vitreous Panel. Diabetic Retinopathy Preferred Practice Pattern Guidelines (2019) https://www.aao.org/preferred-practice-pattern/diabetic-retinopathy-ppp • American Academy of Ophthalmology, Retina/Vitreous Panel. Age-Related Macular Degeneration Preferred Practice Pattern Guidelines (2019) https://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp

In Market Brand

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Drug Name	Information
Sutimlimab-jome (Enjaymo)	**Dose:** Injection: 1,100 mg/22 mL (50 mg/mL) in a single-dose vial. **Indication:** Is a classical complement inhibitor indicated to decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with cold agglutinin disease (CAD). **Comparables:** First FDA approved agent for cold agglutinin disease (CAD). *CAD is a rare autoimmune disorder characterized by the premature destruction of red blood cells (hemolysis). Autoimmune diseases occur when one's own immune system attacks healthy tissue. More specifically, CAD is a subtype of autoimmune hemolytic anemia.* **Guidelines:** Cold Agglutinin Disease - National Organization for Rare Disorders https://rarediseases.org/rare-diseases/cold-agglutinin-disease
Pacritinib (Vonjo)	**Dose:** Capsules: 100 mg Indication: For the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 × 109/L. Comparables: Ruxolitinib (Jakafi), Fedratinib (Inrebic) Guidelines: NCCN Guidelines – Myeloproliferative Neoplasms (Version 1.2022 – February 28,2022)
Ciltacabtagene autoleucel (Carvykti)	**Dose:** Suspension for intravenous infusion. A single dose of CARVYKTI contains a cell suspension of 0.5-1.0×106 CAR-positive viable T cells per kg body weight in one infusion bag. **Indication:** For the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-CD38 monoclonal antibody. **Comparables:** Idecabtagene vicleucel (Abecma), Belantamab mafodotin-blmf (Blenrep) **Guidelines:** NCCN Guidelines – Multiple Myeloma (Version 5.2022 – March 9, 2022)
Filgrastim-ayow (Releuko)	**Dose:** Vial • Injection: 300 mcg/mL in a single-dose vial, • Injection: 480 mcg/1.6 mL in a single-dose vial, Prefilled Syringe Injection: 300 mcg/0.5 mL in a single-dose prefilled syringe, • **Injection:** 480 mcg/0.8 mL in a single-dose prefilled syringe. **Indications:** • To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti- cancer drugs associated with a significant incidence of severe neutropenia with fever. • To reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML). • To reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT). • To reduce the incidence and duration of sequelae of severe neutropenia, (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. *Releuko is biosimilar* to Neupogen® (filgrastim)* **Comparables:** Filgrastim (Neupogen), Filgrastim-sndz (Zarxio), Filgrastim-aafi (Nivestym)

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

First-Time Generic Approval

Generic Name	Applicant	Brand Name	Approval Date	Indication
Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, Amphetamine Sulfate (Mixed Salts of a Single-Entity Amphetamine Product) Extended-Release Capsules, 12.5 mg, 25 mg, 37.5 mg and 50 mg	Teva Pharmaceuticals USA, Inc.	Mydayis (Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, Amphetamine Sulfate)Extended-Release Capsules	01/31/2022	For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 13 years and older.
Brimonidine Tartrate Ophthalmic Solution, 0.15%	Apotex Inc.	Alphagan P (Brimonidine Tartrate) Ophthalmic Solution	01/31/2022	For the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.
Sofosbuvir Tablets, 400 mg	Teva Pharmaceuticals USA, Inc	Sovaldi (Sofosbuvir) Tablets	1/27/2022	For the treatment of adult patients with genotype 1, 2, 3 or 4 chronic HCV infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen
Carbidopa, Levodopa and Entacapone Tablets, 12.5 mg/50 mg/200 mg, 18.75 mg/75 mg/200 mg, 25 mg/100 mg/200 mg, 31.25 mg/125 mg/200 mg, 37.5 mg/150 mg/200 mg, and 50 mg/200 mg/200 mg	Rising Pharma Holdings, Inc.	Stalevo (Carbidopa, Levodopa and Entacapone) Tablets	1/25/2022	For the treatment of Parkinson's disease.
Pirfenidone Tablets, 267 mg and 801 mg	Teva Pharmaceuticals, USA, Inc.	Esbriet (Pirfenidone) Tablets	1/25/2022	For the treatment of idiopathic pulmonary fibrosis.
Pirfenidone Capsules, 267 mg	Amneal EU, Limited	Esbriet (Pirfenidone) Capsules	1/3/2022	For the treatment of idiopathic pulmonary fibrosis.

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Recall

Date	Brand Name(s)	Product Description	Product Type	Recall Reason Description	Company Name
03/07/2022	Fresenius Kabi USA	Sodium Acetate Injection, USP, 400 mEq/100 mL (4 mEq/mL), 100 mL fill in a 100 mL vial	Drugs	Due to the presence of particulate matter found in reserve and/or stability sample vials	Fresenius Kabi, USA
03/07/2022	Tennessee Technical Coatings Corp.	Hand Sanitizer	Drugs	Product contains methanol	Tennessee Technical Coatings Corp.
03/03/2022	B. Braun Medical Inc.	0.9% Sodium Chloride for Injection USP 250ML in Excel	Drugs	Fluid leakage and low fill volume may cause a lack in sterility	B. Braun Medical Inc.
02/10/2022	Positive-Health	Rise Up Red Edition Capsules	Drugs	Undeclared Tadalafil	Positive-Health
02/09/2022	Celebrate Today	Red Mammoth capsules	Drugs	Undeclared Sildenafil and Tadalafil	Celebrate Today
02/08/2022	Your Favorite Shop	The Red Pill	Drugs	Undeclared Tadalafil	Your Favorite Shop
02/08/2022	MAC DADDY	MAC DADDY RED and PURPLE DIETARY SUPPLEMENTS	Drugs	Undeclared Sildenafil and/or Tadalafil	ABC SALES 1 INC

R&D → FDA Approval → In Market Brand → Generic Available → Off Market

Safety

No new drug safety communications.

Shortages (New)

Date	Drug Name (Shortage Reason)
03/04/2022	Dextrose 10% Injection (Currently in Shortage)
03/04/2022	Dextrose 5% Injection (Currently in Shortage)
03/04/2022	Streptozocin Powder for Injection (Currently in Shortage)
03/03/2022	Dextrose 10% Injection (Currently in Shortage)
02/28/2022	Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate Tablets (Currently in Shortage)
02/28/2022	Imipramine Tablets (Discontinuation)
02/25/2022	Diflunisal Tablets (Currently in Shortage)
02/25/2022	Metaxalone Tablets (Discontinuation)
02/22/2022	Azithromycin (Azasite) Ophtalmic Solution 1% (Currently in Shortage)

References:

For the most up to date list of drug shortages visit:

- https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
- https://www.ashp.org/Coronavirus
  - ASHP is providing free access to its AHFS Clinical Drug Information application, which also includes access to drug shortages information. AHFS Drug Information® - Open Access Effective March 16, 2020
  - Username: ahfs@ashp.org
  - Password: covid-19

Off Market

Sources:

- https://www.ashp.org/COVID-19 t https://www.ashp.org/COVID-19 t
- https://www.cdc.gov/media/releases/2021/s-07082021.html t
- https://www.cdc.gov/mmwr/volumes/70/wr/mm7020e2.htm t
- https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls t
- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts t
- https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-newtherapeutic-biological-products/novel-drug-approvals-2021 t
- https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/firstgeneric-drug-approvals
- https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications
- https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals
- https://www.accessdata.fda.gov/scripts/drugshortages/

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