



PERSPECTIVE ON THE **RX** PIPELINE

Understanding changes in the medication market and their impact.

EnvisionRx continuously monitors the drug pipeline. As treatment options change, we evaluate and share our perspective on the clinical benefits and impact in the market. Our Perspective on the Rx Pipeline reports provide ongoing insights from our team of clinical experts and considerations to protect and improve plan performance.

Included in this Edition

- ▶ Clinical Pipeline
- ▶ Key New Drug Approvals
- ▶ New Indications
- ▶ Upcoming and Recent Generic and Biosimilar Launches
- ▶ FDA Safety Update
- ▶ Drug Shortages and Discontinuations

Clinical Pipeline

PIPELINE STAGE



KTE-X19

Manufacturer: Kite Pharma

Indication/Use: Mantle Cell Lymphoma

Dosage Form: Intravenous

Pipeline Stage: PDUFA 8/10/2020

Mantle cell lymphoma (MCL) is a rare B-cell malignancy belonging to the non-Hodgkin lymphoma (NHL) group of diseases.^[1] The incidence is approximately four to eight cases per million persons per year, affecting 7% of the adult NHL population. MCL has an overly aggressive course and is found at a later stage of disease progression. Overall, response rates of treated patients are high but short-lived, as relapse from remission is common. Salvage therapy explored by providers encourages patients to enroll in clinical trials or high-intensity therapy with high-dose steroids or radiation. Second-line treatment options have no preferred order for use and consensus on best treatment is lacking. Patients often try and fail multiple second-line therapies with uncertain durability of remission and many eventually die from their disease.

Immunotherapy by engineering patients' immune cells to treat cancer is at the forefront of individualized cancer treatment. Immunotherapy consists of a single infusion of chimeric antigen receptor-T cell therapy (CAR-T), which enlists T-cells to provide an immune response against a patient's cancer cells. By separating out a patient's T-cells from their own blood sample using genetic engineering, patient-specific chimeric antigen receptors are produced. These T-cells can now recognize and attach to a specific tumor cell receptor. Once administered, following an eradication of immunosuppressive cells by chemotherapy, the engineered T-cells will multiply, ultimately recognizing and killing targeted cancer cells.^[2]

Kite Pharma, a subsidiary of Gilead Sciences, has a pipeline investigational anti-CD19 CAR-T therapy, KTE-X19, for the treatment of relapsed or refractory MCL. In the ZUMA-2 clinical trial, 74 patients with MCL who relapsed or tried and failed five or more previous therapies were evaluated. Patients underwent conditioning chemotherapy with cyclophosphamide and fludarabine, followed by a single infusion of KTE-X19 dosed 2×10^6 CAR-T cells per kilogram of body weight. The overall response rate (ORR), measured as a complete or partial response of a 30% decrease in target lesions, was assessed by an independent radiologic review committee. The primary efficacy analysis was performed on 60 patients. Of the cohort, 93% of patients responded to a single infusion of KTE-X19, with 67% of those having a complete response at a median follow up of 12.3 months.^[3,4] Fifty-seven percent of the 60 patients were in remission. At 12 months, the estimated progression-free survival and overall survival rates were 61% (95% CI, 45–74) and 83% (95% CI, 71–91), respectively. CAR-T therapy is not devoid of side-effects, however. The toxicity profile of KTE-X19 was analogous with previous predecessor data and included grade ≥ 3 toxicities, such as infections, cytokine release syndrome, neurologic events and cytopenias in 94% of patients.^[3]

Costs for approved CAR-T therapies range from \$373,000 up to \$475,000 for a one-time treatment. When factoring in hospitalization and standard of care, CAR-T is speculated to cost nearly \$1 million per patient.^[5]

While other non-CAR-T FDA-approved treatment options for relapsed/refractory MCL exist, short duration of remission and lack of head-to-head trial data leave a gap in guideline recommendations for this population. The successful manufacturing of KTE-X19 and proven efficacy in the phase II ZUMA-2 trial provide promising results for future treatment and the advancement of CAR-T therapy.

Clinical Pipeline

PIPELINE STAGE



Valrox *valoctocogene roxaparvovec*

Manufacturer: BioMarin

Indication/Use: Hemophilia A

Dosage Form: Intravenous

Pipeline Stage: PDUFA 8/21/2020

Hemophilia is an inherited, lifelong bleeding disorder resulting from a deficiency or dysfunction of coagulation factor VIII (hemophilia A) or factor IX (hemophilia B). According to the Centers for Disease Control and Prevention (CDC), the incidence of hemophilia is about one out of every 5,000 male births. It is estimated that 20,000 to as many as 33,000 males are living with hemophilia in the United States. Hemophilia A is four times more common than hemophilia B. Half of the hemophilia A population suffers from a severe form of the disease, defined as factor level ≤ 1 IU per deciliter.^[6] Severe hemophilia A patients use factor concentrates, either intravenously or subcutaneously, multiple times a week to prevent bleeds. This therapy is expensive and patients often develop inhibitors that complicate treatment regimens.

Valoctocogene roxaparvovec is a single infusion investigational gene therapy in the pipeline that works by using vector mediated gene transfer of human factor VIII. It has the potential to reshape hemophilia A treatment by introducing exogenous DNA into a person's cells to produce the missing factors. Valoctocogene roxaparvovec is currently in phase III clinical trials with the potential to be the first hemophilia gene therapy to market.^[7]

A phase 1/2 study showed durable efficacy, long-term safety, and clinical and biologic results in 15 adult men with severe hemophilia A (factor VIII level, ≤ 1 IU per deciliter) who had received a single infusion of valoctocogene roxaparvovec at various dosages. At baseline pre-infusion, patients enrolled had an average annualized bleed rate (ABR) of 16.3 episodes per year. Three years after infusion, patients in the high-dose cohort had a 96% reduction in their mean ABR and the same reduction in exogenous factor infusions per year. Two years after infusion, patients in the low-dose cohort had a 92% reduction in their mean ABR and a 95% reduction in exogenous factor infusions per year.^[8] A one-time infusion of valoctocogene roxaparvovec resulted in a sustained, clinically relevant benefit as assessed by bleeding events and use of prophylactic factor in both the three- and four-year follow up study cohorts. In the trial, cumulative mean ABR remained less than one, with only one person in each cohort having a spontaneous bleed. The safety profile remained favorable with transient mild to moderate increases in liver function tests and infusion-related reactions.^[9]

Results from the phase 1/2 study, along with an interim analysis of the ongoing GENE8-1 phase III trial, supported the submission of a biologic license application (BLA) to the FDA.^[10] If approved, valoctocogene roxaparvovec may have gene therapy competition in the pipeline, with giroctocogene fitelparvovec currently enrolling for phase III trials.

While gene therapy is a novel way to treat hemophilia, the high cost may leave payers cautious of the investment. However, early efficacy and safety data point to favorable outcomes in prevention of serious bleeds, and the benefit of reduced factor utilization and risk of severe bleeds may outweigh the proposed cost in this patient population. Valoctocogene roxaparvovec has the potential to revolutionize the standard of care for hemophilia A patients by reducing prophylactic factor use.

Clinical Pipeline

PIPELINE STAGE



viloxazine hydrochloride

Manufacturer: Supernus Pharmaceuticals

Indication/Use: Attention Deficit Hyperactivity Disorder (ADHD)

Dosage Form: Oral

Pipeline Stage: PDUFA 11/08/2020

Attention deficit hyperactivity disorder (ADHD) is one of the most common childhood disorders, with symptoms of hyperactivity, impulsivity and/or inattention that affect cognitive, academic, behavioral, emotional and social functioning.^[11] The overall prevalence of ADHD is variable depending on the age group described. Worldwide prevalence is estimated at 7.2% among children, but community-based samples are somewhat higher at 8.7% to 15.5%.^[12] ADHD is a difficult condition, as children often present with comorbid anxiety, depression and learning disability. Treatment strategies differ based on the age of the patient, however, stimulants are often first-line therapies in preschool-aged children up to 18 years of age. Stimulants as first-line therapies often create the potential for abuse and diversion and may have extensive side effects, including decreased growth velocities, tics, anxiety and sleep disturbances for some patients.

Non-stimulant therapy does currently exist for ADHD, such as Strattera (atomoxetine). However, non-stimulant medications often take time to work, whereas stimulants have a faster onset. Viloxazine hydrochloride is a serotonin norepinephrine modulating agent marketed as a non-stimulant with a unique mechanism of action for the treatment of ADHD. If approved, this will be the first non-stimulant to treat ADHD in a decade that works differently than available treatment options.^[13]

The submission to the FDA is supported by efficacy and safety data from multiple phase III studies that included patients with ADHD aged 6 to 17 years old. The phase III program consists of four clinical studies using the extended-release formulation, evaluating the mean change from baseline to end of study in the ADHD-Rating Scale-V total score for viloxazine hydrochloride vs. placebo.^[14] The 100 mg, 200 mg and 400 mg cohorts all met the primary objective of greater improvements in ADHD-RS-V total score with statistical significance. Viloxazine was able to reduce ADHD symptoms as early as one week in the 100 mg and 200 mg cohorts, offering an advantage over the current non-stimulant market. Overall, treatment was well tolerated, as dropout rates due to adverse events were $\leq 5\%$. Most common adverse events reported were somnolence, headache and decreased appetite.^[15, 16]

Data suggests the observed reduction of symptoms in one week offers an advantage over Strattera, while the non-stimulant nature of viloxazine hydrochloride offers a superior safety profile to stimulants, giving viloxazine hydrochloride the potential to fill gaps in current ADHD care. Head-to-head trials against stimulants have yet to be conducted for efficacy comparison. While not replacing stimulants as the gold standard, viloxazine hydrochloride may be utilized for children with ADHD when a non-stimulant therapy is desired.

Glossary of Terms

BLA - Biologics License Application

NDA - New Drug Application

PDUFA - Prescription Drug User Fee Act

Key New Drug Approvals

PIPELINE STAGE



Audenz™ *influenza A (H5N1) monovalent vaccine, adjuvanted*

Manufacturer: Seqirus

Indication/Use: Influenza A virus H5N1 subtype vaccine

Dosage Form: Intramuscular injection

Traditional or Specialty: Traditional

Timely with the current COVID-19 pandemic, the FDA approved Audenz on January 31, 2020, for H5N1, also known as the “bird flu.” Audenz was developed in anticipation of a possible pandemic if H5N1 became more transmissible between humans. Use will be sparse unless an H5N1 pandemic occurs, and Audenz is intended to be rapidly deployed and stockpiled during a pandemic.

For more information: <https://www.seqirus.us/news/seqirus-announces-us-fda-approval-of-pandemic-influenza-vaccine>

Isturisa® *osilodrostat*

Manufacturer: Recordati Rare Disease, Inc.

Indication/Use: Cushing’s disease

Dosage Form: Oral tablet

Traditional or Specialty: Specialty

On March 6, 2020, the FDA approved Isturisa for the treatment of Cushing’s disease. The gold standard of treatment for Cushing’s disease is surgery, with ketoconazole or metyrapone available as pharmacological options. Isturisa offers a treatment option for adults for whom pituitary surgery is not an option or has not been curative. It requires cortisol levels to be monitored every one to two months and does carry a significant adverse reaction profile with adrenal insufficiency, fatigue, nausea, headache and edema reported in over 20% of the study population.

For more information: <https://www.fda.gov/news-events/press-announcements/fda-approves-new-treatment-adults-cushings-disease>

Key New Drug Approvals

PIPELINE STAGE



Koselugo™ *selumetinib*

Manufacturer: AstraZeneca Pharmaceuticals LP

Indication/Use: Neurofibromatosis type 1 (NF1)

Dosage Form: Oral capsule

Traditional or Specialty: Specialty

Koselugo received breakthrough therapy, orphan drug and rare pediatric disease designation by the FDA and was approved on April 10, 2020. It is a kinase inhibitor of mitogen-activated protein kinases 1 and 2 (MEK1/2), a mechanism used in some already approved oncology medications. However, Koselugo is not an oncology drug, it is intended to treat pediatric patients two years of age and older with neurofibromatosis type 1 (NF1) who develop inoperable plexiform neurofibromas (PN) that lead to patient morbidity. It is important to note that NF1 patients can have varying symptoms and disease severity. NF1 is a lifelong disease. There are currently no treatment guidelines and Koselugo is the first pharmacological FDA-approved treatment option for NF1.

For more information: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-therapy-children-debilitating-and-disfiguring-rare-disease>

Oriahnn™ *elagolix, estradiol, norethindrone acetate*

Manufacturer: Abbvie

Indication/Use: Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids)

Dosage Form: Oral capsule

Traditional or Specialty: Traditional

Uterine fibroids (UF) are benign, smooth muscle neoplasms of the uterus that affect women of reproductive age and may lead to symptoms such as heavy menstrual bleeding, painful periods, abdominal protuberances, pelvic pressure, bladder and/or bowel dysfunction, and painful intercourse in some symptomatic women. Oriahnn is a combination product of elagolix and “add back” hormone therapy containing an estrogen and progesterone derivative. It was approved due to a reduction in heavy menstrual bleeding versus placebo and is to be used for up to 24 months. Oriahnn carries the same warning for bone mineral density decreases as Orilissa® (elagolix).

For more information: <https://news.abbvie.com/news/press-releases/fda-approves-first-oral-medication-for-management-heavy-menstrual-bleeding-due-to-uterine-fibroids-in-pre-menopausal-women.htm>

Key New Drug Approvals

PIPELINE STAGE



Pizensy™ *lactitol monohydrate*

Manufacturer: Braintree Laboratories, Inc.

Indication/Use: Chronic idiopathic constipation (CIC)

Dosage Form: Oral powder for solution

Traditional or Specialty: Traditional

Pizensy is a new hyperosmotic agent that was approved by the FDA on February 12, 2020, to increase bowel movements in adults with chronic idiopathic constipation, a condition with low patient satisfaction from current therapy options.^[17] It is a once daily oral osmotic. Its place in therapy may be after over-the-counter options, such as polyethylene glycol, and lifestyle changes.

For more information: <https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trial-snapshot-pizensy>

Tukysa™ *tucatinib*

Manufacturer: Seattle Genetics, Inc.

Indication/Use: Advanced unresectable or metastatic HER2-positive breast cancer

Dosage Form: Oral tablet

Traditional or Specialty: Specialty

On April 17, 2020, the FDA approved Tukysa for advanced HER2-positive breast cancer, including patients with brain metastases who have received one or more prior HER2-based regimens in the metastatic setting. It's taken in combination with trastuzumab and capecitabine. Clinical studies demonstrated statistically significant progression-free survival compared to trastuzumab and capecitabine therapy alone. Tukysa's indication allowing for inclusion of those with brain metastases may give it a unique place in oncology treatment for these patients.

For more information: <https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshot-tukysa>

New Indications

PIPELINE STAGE



Brilinta[®] *ticagrelor*

Manufacturer: AstraZeneca

Indication/Use: To reduce the risk of cardiovascular (CV) death, myocardial infarction (MI) and stroke in patients with acute coronary syndrome (ACS) or a history of MI

Dosage Form: Oral tablet

Traditional or Specialty: Traditional

Date of Original Approval: July 20, 2011

Brilinta is now indicated to reduce the risk of a first MI or stroke in patients with coronary artery disease (CAD) at high risk for such events. The THEMIS trial compared Brilinta 60 mg and aspirin therapy versus aspirin alone in patients with CAD and type 2 diabetes mellitus with no prior heart attack or stroke. Results showed a statistically significant reduction in major adverse cardiovascular events (primarily heart attack or stroke) at 36 months when used with aspirin.^[18] Note, the FDA-approved indication does not limit to those with type 2 diabetes.

For more information: <https://www.astrazeneca.com/media-centre/press-releases/2020/brilinta-approved-in-the-us-to-reduce-the-risk-of-a-first-heart-attack-or-stroke-in-high-risk-patients-with-coronary-artery-disease.html>

Dupixent[®] *dupilumab*

Manufacturer: Regeneron Pharmaceuticals

Indication/Use: Atopic dermatitis, asthma

Dosage Form: Subcutaneous injection

Traditional or Specialty: Specialty

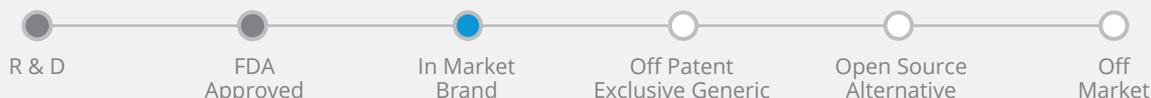
Date of Original Approval: March 28, 2017

Dupixent is now indicated for the treatment of patients aged six years and older with moderate-to-severe atopic dermatitis where topical therapy is ineffective or not advised. Dupixent may offer a safer alternative to first-line immunosuppressive drugs in a disease with a high prevalence in the pediatric population. Studies in children aged six to 11 showed clear skin and less itch, with the added convenience of two to four week maintenance dosing after an initial loading dose.

For more information: <https://www.regeneron.com/dupixent-injection>

New Indications

PIPELINE STAGE



Eucrisa[®] *crisaborole*

Manufacturer: Anacor Pharmaceuticals, Inc.

Indication/Use: Atopic dermatitis

Dosage Form: Topical ointment

Traditional or Specialty: Traditional

Date of Original Approval: December 14, 2016

As of March 23, 2020, Eucrisa is indicated as a topical treatment of mild-to-moderate atopic dermatitis in adult and pediatric patients three months of age or older. It will compete with topical corticosteroids as first-line therapy for this younger population. As a disease mainly represented by pediatric patients, the marginal side effect profile of Eucrisa compared to long-term steroid use at a very young age may provide Eucrisa with an advantage in this market.

For more information: <https://www.pfizer.com/products/product-detail/eucrisa>

Farxiga[®] *dapagliflozin*

Manufacturer: AstraZeneca

Indication/Use: Adjunct to diet and exercise to improve glycemic control in type 2 diabetes mellitus, to reduce risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors

Dosage Form: Oral tablet

Traditional or Specialty: Traditional

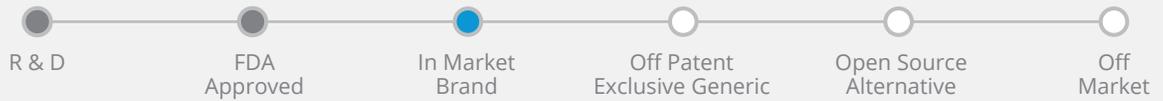
Date of Original Approval: January 08, 2014

Farxiga obtained a new indication in May 2020 to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure with reduced ejection fraction (NYHA class II-IV), regardless of diabetes status. It is the first sodium-glucose co-transporter 2 (SGLT2) inhibitor approved for heart failure with a reduced ejection fraction.

For more information: <https://www.ajmc.com/newsroom/fda-approves-dapagliflozin-to-treat-heart-failure-breaking-new-ground-in-sgl2-competition>

New Indications

PIPELINE STAGE



Lynparza[®] *olaparib*

Manufacturer: AstraZeneca

Indication/Use: Ovarian, breast and pancreatic cancer

Dosage Form: Oral tablet

Traditional or Specialty: Specialty

Date of Original Approval: August 17, 2017

Lynparza tablet received two new indications from the FDA in May 2020:

- In combination with bevacizumab as first-line maintenance treatment of homologous recombination deficiency (HRD-positive) advanced ovarian cancer, following complete or partial response to first-line platinum-based chemotherapy.
- For treatment of somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer, following progression on enzalutamide or abiraterone.

Both indications should be selected after results from an FDA-approved companion diagnostic agent.

For more information: <https://www.lynparzahcp.com/>

Ofev[®] *nintedanib*

Manufacturer: Boehringer Ingelheim

Indication/Use: Idiopathic pulmonary fibrosis (IPF) with systemic sclerosis-associated interstitial lung disease (ILD)

Dosage Form: Oral capsule

Traditional or Specialty: Specialty

Date of Original Approval: October 15, 2014

Ofev received FDA approval on March 9, 2020, for treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype. The treatment slows the rate of decline in pulmonary function in patients with systemic sclerosis-associated ILDs. Many diseases may develop into progressive chronic fibrosing ILDs, such as unclassifiable ILDs, autoimmune ILDs, chronic hypersensitivity pneumonitis, sarcoidosis, myositis, sjogren's syndrome, coal workers pneumoconiosis and idiopathic forms of interstitial pneumonias, such as idiopathic non-specific interstitial pneumonia.

For more information: <https://www.boehringer-ingelheim.us/press-release/fda-approves-ofev-first-treatment-chronic-fibrosing-ilds-progressive-phenotype>

New Indications

PIPELINE STAGE



Reblozyl[®] *luspatercept-aamt*

Manufacturer: Bristol Myers Squibb

Indication/Use: Beta thalassemia

Dosage Form: Subcutaneous injection

Traditional or Specialty: Specialty

Date of Original Approval: November 08, 2019

On April 3, 2020, the FDA approved Reblozyl for a second indication of the treatment of adult patients with anemia associated with myelodysplastic syndromes with ring sideroblasts or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis. The MEDALIST trial reported a statistically significant greater portion of patients in the Reblozyl treatment arm versus placebo achieved at least 12 weeks of blood transfusion independence (28% vs. 8% for weeks one through 24, and 33% vs. 12% for weeks one through 48; $P < 0.001$ for both comparisons).^[19]

For more information: <https://www.reblozyl.com/>

Taltz[®] *ixekizumab*

Manufacturer: Lilly

Indication/Use: Plaque psoriasis, psoriatic arthritis, ankylosing spondylitis

Dosage Form: Subcutaneous injection

Traditional or Specialty: Specialty

Date of Original Approval: March 22, 2016

Taltz had two recent indication updates. In March 2020, Taltz's psoriasis indication was expanded to allow for treatment in those six years of age and older with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. In May 2020, Taltz received FDA approval for treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of Inflammation. In non-radiographic axial spondyloarthritis (nrAxSpA) patients have symptoms much like ankylosing spondylitis, but do not have abnormalities of the sacroiliac joints upon X-ray.^[20] Non-steroidal anti-inflammatory medications are usually first-line medication for nrAxSpA, and Cimzia (certolizumab pegol) also shares the nr-axSpA FDA-approved indication.

For more information: <https://www.taltz.com/nr-axspa>

Upcoming and Recent Generic and Biosimilar Launches

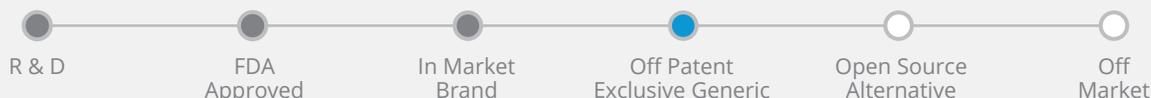
PIPELINE STAGE



Brand Name	Generic Name	# of Manufacturer Entrants	Indication	Anticipated Launch Date
Aptensio™ XR	methylphenidate hydrochloride	1	Attention-deficit/hyperactivity disorder	Launched
Atripla®	efavirenz; emtricitabine; tenofovir disoproxil fumarate	1	HIV-1 infection	09/30/2020
Bidil®	hydralazine hydrochloride; isosorbide dinitrate	TBD	Heart failure	09/08/2020
Denavir®	peniclovir sodium	TBD	Herpes labialis (cold sores)	TBD
Dymista®	azelastine hydrochloride; fluticasone propionate	1	Seasonal allergic rhinitis	Launched
Geodon® (injection)	ziprasidone mesylate	1	Agitation, acute associated with psychiatric disorders	Launched
Herzuma® Biosimilar – Originator Herceptin	trastuzumab-pkrb	1	Adjuvant breast cancer, metastatic breast cancer, metastatic gastric cancer	Launched
Insulin Lispro® Mix (Authorized of Humalog Mix 75/25 KwikPen)	insulin lispro protamine recombinant; insulin lispro recombinant	1	Diabetes mellitus	Launched
Korlym®	mifepristone	1	Hyperglycemia secondary to hypercortisolism in patients with endogenous Cushing's syndrome	2H 2020
Kuvan® (100 mg powder and tablet)	sapropterin dihydrochloride	1	Metabolic, endocrine and nutritional diseases (not otherwise classified), hyperphenylalaninemia due to tetrahydrobiopterin- (BH4-) responsive phenylketonuria	10/01/2020
Marqibo® Kit	vincristine sulfate	TBD	Acute lymphocytic leukemia	09/25/2020

Upcoming and Recent Generic and Biosimilar Launches

PIPELINE STAGE



Brand Name	Generic Name	# of Manufacturer Entrants	Indication	Anticipated Launch Date
Mycamine®	miconazole sodium	1	Fungal infections (candidiasis) treatment and prophylaxis	Launched
Nexium® (2.5 mg, 5 mg, 10 mg packets for oral suspension)	esomeprazole magnesium	1	Gastroesophageal reflux disease (GERD), Helicobacter pylori eradication	Launched
Nexium® (20 mg and 40 mg packets for oral suspension)	esomeprazole magnesium	1	Gastroesophageal reflux disease (GERD), Helicobacter pylori eradication	Launched
Ontruzant® Biosimilar – Originator Herceptin	trastuzumab-dttb	1	Adjuvant breast cancer, metastatic breast cancer, metastatic gastric cancer	Launched
Osmoprep®	sodium phosphate, dibasic, anhydrous; sodium phosphate, monobasic, monohydrate	1	Bowel cleansing	TBD
Risperdal Consta®	risperidone	TBD	Schizophrenia, bipolar disorder	11/26/2020
Samsca®	tolvaptan	2	Hypervolemic or euvolemic hyponatremia	Launched
Saphris®	asenapine maleate	4	Schizophrenia, bipolar disorder	TBD
Tirosint®	levothyroxine sodium	1	Thyroid cancer, differentiated thyroid cancer, hypothyroidism	3Q 2020
Trazimera™ Biosimilar – Originator Herceptin	trastuzumab-qyyp	1	Adjuvant breast cancer, metastatic breast cancer, metastatic gastric cancer	Launched

Upcoming and Recent Generic and Biosimilar Launches

PIPELINE STAGE



Brand Name	Generic Name	# of Manufacturer Entrants	Indication	Anticipated Launch Date
Truvada® (200 mg/300 mg)	emtricitabine; tenofovir disoproxil fumarate	1	HIV-1 infection, prophylaxis to reduce risk of sexually acquired HIV-1	09/30/2020
Tykerb®	lapatinib ditosylate	1	HER2-positive breast cancer	09/29/2020
Zortress®	everolimus	1	Prophylaxis for organ rejection for liver and renal transplant	Launched

FDA Safety Updates

Drug Safety Communication

FDA alerts auto-injector issues with Amneal and Impax Laboratories epinephrine devices and EpiPen®

Two FDA safety alerts were released recently regarding epinephrine auto-injectors, which are used to treat allergic reactions, including anaphylaxis. On March 24, 2020, an alert was given to patients, healthcare professionals and caregivers that the EpiPen 0.3 mg and EpiPen Jr 0.15 mg may potentially have delayed injection. Altering the blue safety release and incorrect use of these products may increase error. It is suggested that these products be inspected to check the device can be easily removed from the carrier tube and the blue safety release is not raised. Healthcare providers should also make sure patients and caregivers are properly educated on administration technique. At this time, the FDA did not issue a recall on these EpiPen products.

On June 1, 2020, the FDA released an alert for patients, caregivers and healthcare professionals to check for the yellow “stop collar” on Amneal and Impax epinephrine auto-injector 0.3 mg. Instructions on how to inspect and confirm the presence of the yellow “stop collar” can be found at the link below. If there is no yellow stop collar, patients and healthcare professionals should contact the Amneal Drug Safety department.

For more information: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-patients-and-health-care-professionals-amneal-and-impax-laboratories-epinephrine-auto>

<https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-patients-and-health-care-professionals-epipen-auto-injector-errors-related-device>

Drug Shortages and Discontinuations

COVID-19's Impact on Drug Shortages

The recent pandemic has brought attention to drug shortages. Concerns of supply chain demand on available inventories and product production issues loom. The FDA states any shortage related to COVID-19 are to be posted on the FDA Drug Shortages webpage. The FDA posts a drug on the shortage website if: “the manufacturers provide information regarding their ability to supply the market, the FDA receives market sales data on specific products, or the FDA has confirmed that overall market demand is not being met by the manufacturers of the product.” The FDA does not consider a product to be in shortage if one or more manufacturers are able to fully supply market demand for the product.

Early in the pandemic shortages were seen in face masks, hand sanitizers and personal protective equipment. Currently, most drug products in shortage are hospital-administered medications, such as injectable analgesics, sedatives and paralytics for intubating ill patients. Concerns occurred over a hydroxychloroquine and chloroquine shortage, as chloroquine was reported in shortage, but with the drugs recent removal from the FDA Emergency Authorized Use list, product availability may rebound shortly. Dexamethasone sodium phosphate injection has been reported in shortage, as some evidence is building to support its use in hospitalized patients with severe respiratory complications of COVID-19.

For more information on drug shortages: <https://www.fda.gov/drugs/coronavirus-covid-19-drugs/drug-shortages-response-covid-19>

<https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>

[https://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(20\)30136-4/fulltext](https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(20)30136-4/fulltext)

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