PERSPECTIVE ON THE RX PIPELINE

FDA UPDATES

Understanding changes impacting the pharmaceutical landscape and providing the latest industry news.

EnvisionRx continuously monitors the drug pipeline. Our clinical information team provides a resource for major drug industry news in order to educate and inform our clients as new drugs are approved, generics launch and current medications receive new indications.

Included in this Edition

- FDA Drug Approvals for February 2018
- New Indications
- Generic Approvals Now Available
- FDA Safety Update

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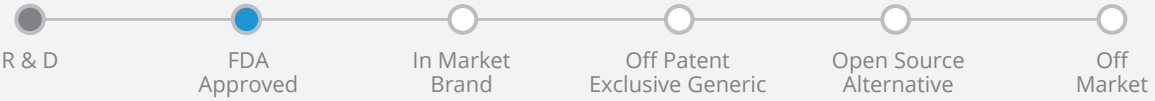
Drug Approvals

PIPELINE STAGE



Biktarvy® *bictegravir, emtricitabine and tenofovir alafenamide*

Manufacturer: Gilead Sciences, Inc.
Indication/Use: HIV Infection
Dosage Form: Tablet
Traditional or Specialty: Traditional

Gilead Science announced that the FDA approved Biktarvy (bictegravir, emtricitabine and tenofovir alafenamide) on February 7, 2018. This fixed dose combination product contains a new unboosted integrase strand transfer inhibitor, bictegravir with a Descocy (emtracitabine/tenofovir alafenamide) backbone. Biktarvy's FDA labeled indications include the treatment of HIV-1 infection in adults who have never been treated or to replace an adult patient's current regimen if they meet specific clinical requirements.

For more information: https://www.biktarvy.com/

Dexycu™ *dexamethasone*

Manufacturer: Icon Bioscience, Inc.
Indication/Use: Postoperative Ocular Inflammation
Dosage Form: Intraocular Suspension
Traditional or Specialty: Traditional

The FDA's approval of Dexycu (dexamethasone) on February 12, 2018, provides a new treatment option for inflammation after cataract surgery. Cataract surgeons now have the option of a single intraocular injection at the site of action at the conclusion of surgery, eliminating the need for patient administered eye drops.

For more information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/208912s000lbl.pdf

Erleada™ *apalutamide*

Manufacturer: Janssen Pharmaceuticals, Inc.
Indication/Use: Prostate Cancer
Dosage Form: Tablet
Traditional or Specialty: Specialty

The FDA announced on February 14, 2018, the approval of Erleada (apalutamide) for the treatment of prostate cancer in patients in which the cancer has not spread (non-metastatic), but is progressing even with hormone therapy. Erleada is the first FDA-approved cancer therapy for these specific patients. By blocking the effect of hormones on the tumor, Erleada can stop the promotion of tumor growth that occurs from the hormones.

For more information: https://www.erleada.com/

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Drug Approvals

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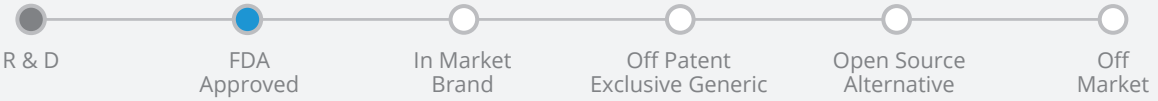


Osmolex ER™ *amantadine hydrochloride*

Manufacturer: Osmotica Pharmaceutical US LLC
Indication/Use: Parkinson's disease, Extrapyramidal Reaction
Dosage Form: Extended-Release Tablet
Traditional or Specialty: Specialty

Osmolex ER (amantadine ER), a combination of immediate-release and extended-release amantadine, was approved February 19, 2018 by the FDA to treat drug-induced movement disorders associated with Parkinson's disease. Osmolex ER should be taken in the morning and provides a controlled release of medication throughout the day. Another extended-release version of amantadine was approved in the fall of 2017, Gocovri™, by Adamas Pharmaceuticals.

For more information: http://www.osmotica.com/PDF/Osmotica_Release_2_19_18_FINAL.pdf and https://www.gocovri.com/

Symdeko™ *ivacaftor/tezacaftor and ivacaftor*

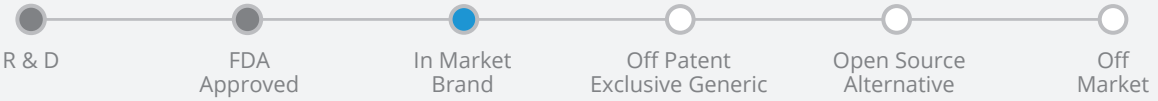
Manufacturer: Vertex Pharmaceuticals, Inc.
Indication/Use: Cystic Fibrosis
Dosage Form: Tablet
Traditional or Specialty: Specialty

On February 13, 2018, the FDA approved Symdeko (tezacaftor/ivacaftor and ivacaftor) to treat cystic fibrosis (CF) patients that have two copies of the F580del mutation gene or have one mutation that is responsive to tezacaftor/ivacaftor. The action of Symdeko against certain gene mutations promotes treatment of the underlying cause of CF and demonstrates improvements in lung function with sustained responses up to 48 weeks in clinical trials.

For more information: https://www.symdeko.com/

New Indications

PIPELINE STAGE



Imfinzi® *durvalumab*

Manufacturer: Astra Zeneca
Indication/Use: Metastatic Urothelial Carcinoma and Stage III Non Small Cell Lung Cancer (NSCLC)
Dosage Form: Injection
Traditional or Specialty: Specialty
Date of Original Approval: May 1, 2017

Imfinzi is an anti-PD-L1 (programmed death ligand-1) human monoclonal antibody for the treatment of patients with metastatic urothelial carcinoma. On February 16, 2018, the FDA approved the expanded indication to patients with stage III NSCLC whose tumor could not be surgically removed and has not progressed after chemotherapy and radiation. This is the first treatment approved for these patients and offers an approved therapy to keep the cancer from progressing for a longer time after chemoradiation.

For more information: https://www.imfinzi.com/

Zytiga® *abiraterone acetate*

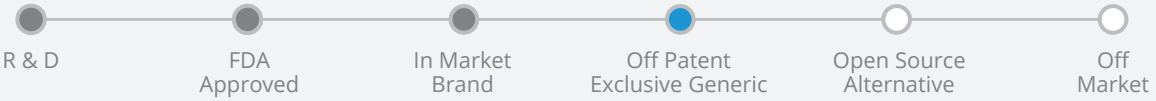
Manufacturer: Janssen Pharmaceutical Company
Indication/Use: Metastatic Castration-Resistant Prostate Cancer and Metastatic High-Risk Castration-Sensitive Prostate Cancer
Dosage Form: Tablet
Traditional or Specialty: Specialty
Date of Original Approval: April 28, 2011

Zytiga is a CYP17 inhibitor indicated for the treatment of patients with metastatic castration-resistant prostate cancer. The Janssen Pharmaceutical Company announced that the FDA approved an expanded indication for Zytiga in combination with prednisone for the treatment of patients with metastatic high-risk castration-sensitive prostate cancer. Patients with newly diagnosed metastatic disease and high-risk disease characteristics tend to have a poorer prognosis. Now, Zytiga provides an option for treatment in these patients that has demonstrated improvement in overall survival.

For more information: https://www.zytiga.com/

Generic Approvals Now Available

PIPELINE STAGE



Brand Name	Generic Name	# of Entrants*	Name of Entrants	Indication
Namenda XR®	Memantine Hydrochloride	4	Amneal, Lupin, Par, Mylan	Dementia associated with Alzheimer's disease
Locoid® lotion	Hydrocortisone Butyrate	3	Oceanside, Actavis/Teva, Glenmark	Dermatitis or Eczema
Syprine®	Trientine Hydrochloride	3	Oceanside, Teva, Kadmon	Wilson's disease
Sustiva® 600mg	Efavirenz	1	Mylan	HIV
Solodyn®	Minocycline Hydrochloride	2	Impax, Teva	Acne Vulgaris

* Indicates the number of manufacturers launching a generic to the brand product. Typically pricing is more competitive the more generics that launch.

FDA Safety Updates

Drug Safety Communication

Biaxin® (clarithromycin) - On February 22, the FDA issued a drug safety communication advising caution before health professionals prescribe Biaxin to patients with heart disease. This recommendation is based on a review of the results of a 10-year follow-up study of patients with coronary heart disease, which showed a potential increased risk in heart problems or death that can occur years later. Health professionals should be aware of these significant risks and weigh all options before prescribing to any patient, specifically in patients with heart disease, even for short periods. **For more information:** https://www.fda.gov/Drugs/DrugSafety/ucm597289.htm

Ocaliva® (obeticholic acid) - The FDA distributed a drug safety communication on February 21 indicating an increased risk of serious liver injury from Ocaliva. This led to the addition of a boxed warning to highlight this information on the prescribing drug label. The FDA is also requiring a medication guide for patients to inform them about this issue. Ocavliva is being incorrectly dosed daily instead of weekly in patients with moderate to severe primary biliary cholangitis (PBC). In response to the September 2017 issue of the ***MedWatch*** safety alert regarding the increased risk of serious liver injury due to the incorrect dosing, the FDA's highest warning has been added.

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Our Clinical Steering Committee

The Envision Clinical Steering Committee brings together leaders from across our national pharmacy care company to monitor the drug landscape, provide recommendations on how to address changes, and to ensure our clients and patients are prepared—in advance.

With any new development, we partner with our Pharmacy & Therapeutics (P&T) Committee and consult with our best-in-class specialty pharmacy, to provide a balanced perspective on the clinical effectiveness of all available options, the cost impact to our plan sponsors and patients, and the impact on the overall patient experience.

Kel Riley, MD
Chief Medical Officer

Learn more ways to improve patient and plan outcomes

visiblydifferent.envisionrx.com

Sources

Fizazi K., et al. LATITUDE: A phase III, double-blind, randomized trial of androgen deprivation therapy with abiraterone acetate plus prednisone or placebos in newly diagnosed high-risk metastatic hormone-naive prostate cancer. ASCO 2017. Abstract #LBA3.

https://www.ashp.org/Drug-Shortages/Current-Shortages

https://www.fda.gov/Drugs/DrugSafety/ucm597289.htm

https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm594901.htm

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EnvisionRx is a Pharmacy Benefit Manager (PBM), providing affordable and effective prescription drug coverage for employers and health plans. Using its proprietary EnvisionCare model, EnvisionRx optimizes all aspects of the pharmacy care experience to consistently achieve better patient and plan outcomes.

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