

New Application Approval

Abiraterone acetate

Approved date: July 20, 2017

Treatment for: **Prostate Cancer**

Abiraterone acetate is an improved ultramicrosize formulation of the oral CYP17 inhibitor abiraterone acetate (approved as Zytiga) in development for the combination treatment of metastatic castration-resistant prostate cancer.

Buprenorphine

Approved date: July 20, 2017

Treatment for: **Opiate Dependence**

Buprenorphine is a long-acting partial opioid agonist formulation in development for the treatment of opioid dependence.

Erenumab

Approved date: July 20, 2017

Treatment for: **Migraine Prophylaxis**

Erenumab is a human monoclonal antibody that inhibits the receptor for calcitonin gene-related peptide (CGRP) in development for the prevention of episodic and chronic migraine.

Romozosumab

Approved date: July 16, 2017

Treatment for: **Osteoporosis**

Romozosumab is an anti-sclerostin monoclonal antibody in development for the treatment of osteoporosis in postmenopausal women at increased risk of fracture.

Abemaciclib

Approved date: July 12, 2017

Treatment for: **Breast Cancer**

Abemaciclib is a selective ATP-competitive inhibitor of cyclin dependent kinases (CDK) 4 and 6 in development for the treatment of metastatic breast cancer.

Migalastat

Approved date: July 11, 2017

Treatment for: **Fabry Disease**

Migalastat is an investigational pharmacological chaperone in development for the treatment of Fabry disease.

Dexamethasone (Intracanalicular Depot)

Approved date: July 11, 2017

Treatment for: **Postoperative Ocular Inflammation**

Dexamethasone is an investigational intracanalicular depot corticosteroid formulation designed to deliver sustained release dexamethasone to the ocular surface for up to 30 days after ophthalmic surgery for the treatment of post-surgical ocular inflammation and pain.

Entrectinib

Approved date: July 10, 2017

Treatment for: **Neuroblastoma**

Entrectinib is a potent, novel, orally available, selective tyrosine kinase inhibitor in development for the treatment of neuroblastoma.

Cyclobenzaprine hydrochloride

Approved date: July 10, 2017

Treatment for: **Post Traumatic Stress Disorder**

Cyclobenzaprine is a sublingual formulation of an approved skeletal muscle relaxant in development for the treatment of patients with post-traumatic stress disorder (PTSD).

Treprostinil

Approved date: June 30, 2017

Treatment for: **Pulmonary Arterial Hypertension**

Treprostinil is a preservative-free, parenteral formulation of the approved vasodilatory prostacyclin analogue treprostinil delivered via the proprietary

PatchPump infusion system for the treatment of pulmonary arterial hypertension (PAH).

Levodopa (Inhalation Powder)

Approved date: June 29, 2017

Treatment for: **Parkinson's disease**

Levodopa is an oral inhalation formulation of the approved drug levodopa in development as a treatment for symptoms of OFF periods in people with Parkinson's disease taking a carbidopa/levodopa regimen.

Fostamatinib

Approved date: June 19, 2017

Treatment for: **Immune Thrombocytopenia**

Fostamatinib is an investigational oral spleen tyrosine kinase (SYK) inhibitor in development for the treatment of patients with chronic and persistent immune thrombocytopenia (ITP).

Bictegravir, Emtricitabine & Tenofovir Alafenamide

Approved date: June 12, 2017

Treatment for: **HIV Infection**

Bictegravir, emtricitabine and tenofovir alafenamide is an investigational integrase strand transfer inhibitor and emtricitabine/tenofovir alafenamide (FTC/TAF) combination in development for the treatment of HIV-1 infection in adults.

Source: drugs.com

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