Retiree Rx Care

NEW DRUG REPORT: 1ST QUARTER 2020

EXISTING DRUG UPDATES

Voltaren® Gel (diclofenac sodium): The U.S. Food and Drug Administration (FDA) changed the status of GlaxoSmithKline's Voltaren® Gel 1% from prescription to non-prescription. The new over the counter product will be marketed as Voltaren® Arthritis Pain (diclofenac sodium topical gel, 1%) and like the prescription product, is also indicated for the temporary relief of joint pain due to osteoarthritis.

AJOVY® (fremanezumab-vfrm): The FDA has approved an autoinjector device from Teva Pharmaceuticals USA, Inc. for AJOVY® injection expected to be available to patients in the coming months. AJOVY® is an antibody administered either monthly or quarterly to prevent migraines. With this approval, the medication will no longer have to be administered using a syringe, and the company will be able to package its medicine within the device, which patients prefer.

FIRST TIME GENERIC APPROVALS

Pyrimethamine Tablets: Cerovene, Inc. has been approved by the FDA to produce a generic alternative to DARAPRIM® (pyrimethamine) as an antimalarial therapy for the treatment of toxoplasmosis, a parasitic infection, when used concurrently with a sulfonamide antibiotic. The generic availability date is unclear, as is the cost per 25mg pill. (DARAPRIM® is currently $750/ 25mg pill.)

Dabigatran Etexilate Capsules: The approval to produce a generic alternative to PRADAXA® (dabigatran etexilate) was granted to Alken Laboratories Limited by the FDA. The medication is designed to reduce the risk of stroke and systemic blood clotting in patients with non-valvular atrial fibrillation, and is also approved for the treatment of deep venous blood clotting and clotting in the lungs. The generic drug was approved 3/11/2020 and availability and cost information has yet to be released.

Dihydroergotamine Mesylate Nasal Spray: Custopharm, Inc. has been approved by the FDA to produce a generic alternative to MIGRANAL® (dihydroergotamine mesylate) Nasal Spray for the immediate relief of migraine headaches with and without aura or any other ocular symptoms. Drug launch date and estimated costs unknown.

Albuterol Sulfate Inhalation Aerosol: The FDA granted Perrigo Pharmaceuticals Company approval to produce a generic inhalation aerosol alternative to ProAir® HFA (albuterol sulfate). Expected to cost less than 50% what ProAir® HFA is sold for, Perrigo's aerosol has the same indication as its competitor; for the treatment or prevention of asthma attacks in patients 4 years of age and older with reversible obstructive airway disease, and the prevention of exercise-induced asthma attacks in patients 4 years of age and older. It is expected to be available to the public in late 2020.

Olopatadine Hydrochloride Ophthalmic Solution/ Drops 0.7%: The FDA approved Watson Laboratories to produce a generic alternative to PAZEO® (olopatadine hydrochloride) Ophthalmic Solution for the treatment of ocular itching associated with allergic conjunctivitis ("allergy eye"). Expected price and public launch date is unknown.

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Naproxen and Esomeprazole Magnesium Delayed- Release Tablets: Dr. Reddy's Laboratories was approved by the FDA to produce a generic alternative to VIMOVO® (naproxen/ esomeprazole magnesium) Delayed- Release Tablets. The tablets are indicated for the symptomatic relief of arthritis, and to decrease the risk of developing NSAID-associated stomach ulcers. Expected cost and public availability date is unknown.

Sodium Iodide I 131 Solution & Capsules: International Isotopes, Inc. has been approved by the FDA to produce generic versions of HICON® (sodium iodide-i-131) Solution and Capsules for the treatment of hyperthyroidism and select cases of thyroid cancer. The generic drug's projected cost and availability date is unknown.

Hydrocodone Bitartrate Extended Release Capsules: The FDA approved Alvogen Malta Operations Ltd. to produce a generic version of Zohydro™ (hydrocodone bitartrate) ER Capsules. Both products are indicated for the management of pain severe enough to require daily, around the clock, long-term opioid treatment and for which alternative treatment options are inadequate. To reduce the risk of toxic liver disease resulting from long term use, this is a acetaminophen free medication. Cost and public availability date is unknown.

NEW BRAND NAME DRUG APPROVALS

AYVAKIT™ (avapritinib): The FDA approved Blueprint Medicines' AYVAKIT™ oral tablet. It is the first targeted therapy to treat a rare mutation in adults with a specific type of advanced tumor that occurs in the gastrointestinal tract, most commonly in the stomach or small intestine. The most common mutation is resistant to all other approved therapies, however, when tested, AYVAKIT™ had an overall response rate of 84% in patients with the mutation. The estimated cost at launch is $32,000/month.

TEPEZZA™ (teprotumumab-trbw): Horizon Therapeutics Ireland's TEPEZZA™ injection has been approved by the FDA as the first and only FDA-approved prescription treatment for thyroid eye disease, a rare condition where the tissue behind the eye becomes inflamed, causing the eye to bulge outwards. TEPEZZA™ was approved based on the results of two studies consisting of 170 patients with active thyroid eye disease who were randomized to either receive TEPEZZA™ or a placebo. Of the patients who were administered TEPEZZA, an average of 77% of patients demonstrated a bulge reduction greater than 2mm, compared only 15% of subjects who received the placebo. Monthly costs are expected to be approximately $33,000, with full treatment over 6 months costing around $200,000.

TAZVERIK™ (tazemetostat): The FDA granted Epizyme Inc. accelerated approval for their TAZVERIK™ oral tablet to treat individuals aged 16+ with epithelioid sarcoma, a rare, slow growing soft tissue cancer. TAZVERIK™ is the second targeted therapy approved for a soft tissue cancer, and the first treatment option specifically for epithelioid sarcoma, granting it orphan drug designation. TAZVERIK™ is taken twice daily and works by blocking specific enzyme activity to help prevent cancer cells from growing. During clinical trials, 67% of patients who had positive results with TAZVERIK™ had responses lasting 6 months or longer. Average monthly cost is approximately $15,500.

PIZENSY (lactitol): The FDA approved Braintree Labs' PIZENSY oral solution for adults with chronic idiopathic constipation (CIC). PIZENSY is an osmotic laxative crystalline powder intended to be mixed with common beverages that works by increasing the flow of water into the intestines to produce softer and easier-to-pass stools. PIZENSY will be sold in multi dose bottles and 10-gram unit-dose packets. It can be safely administered daily if necessary. It is expected to be patent protected and available to the public later in 2020.

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NEW DRUG REPORT: 1ST QUARTER 2020

NEXLETOL™ (bempedoic acid): NEXLETOL™ oral tablets from Esperion Therapeutics Inc. have recently been approved by the FDA for treatment of adults with inherited genetic high cholesterol or established cardiovascular disease who require additional LDL cholesterol lowering. NEXLETOL™ is to be administered as an adjunct to maximally tolerated statin therapy and the maintenance of a proper diet. NEXLETOL™ will be commercially available in the U.S., by prescription only, on March 30, 2020 for an estimated monthly cost of $300 before insurance coverage.

VYEPTI™ (eptinezumab-jjmr): VYEPTI™ is a 30-minute, FDA approved intravenous (IV) infusion administered once every 3 months for the preventative treatment of migraines in adults from Lundbeck Seattle Biopharmaceuticals, Inc. VYEPTI™ is the first and only IV preventative treatment for migraines, and in two clinical studies, VYEPTI™ resulted in a decrease in mean monthly migraine days (MMD) over 6 months. The treatment benefit over placebo was observed for both rounds of VYEPTI™ as early as 1-day post-infusion and demonstrated a sustained reduction of MMD through month six. The treatment will be available as early as April 2020 for an average monthly cost of $575.

BARHEMSYS® (amisulpride): The FDA recently approved Acacia Pharma's BARHEMSYS®, an intravenous formulation of amisulpride, for the treatment of postoperative (and chemotherapy induced) nausea and vomiting (PONV), alone and in combination with other anti-PONV drugs. Approval was given due to the positive results of four clinical trials investigating the treatment of established PONV with and without standard anti-PONV treatment, and the prevention of PONV. Launch is planned for the second half of 2020.

Nurtec ODT™ (rimegepant): Nurtec ODT™ orally disintegrating tablets from BioHaven Pharmaceuticals Holding Co. Limited are the first and only FDA approved orally dissolving CGRP receptor antagonist for the acute treatment of migraine in adults. Nurtec ODT™ works by blocking the effects of CGRP, a protein that is highly prevalent in the sensory nerves that supply the head and the neck, to relieve acute migraine symptoms. Nurtec ODT™ is not to be administered as a preventative therapy, and should be taken as needed up to once daily for up to 48 hours of relief. Quick dissolving ODT™ can start working in minutes, and people taking Nurtec ODT™ experienced relief from their most bothersome symptoms in just 2 hours vs. placebo. Nurtec is now available in 8-pill packages for prescription in the U.S. and will cost ~$4,500/year for the average consumer before insurance or discounts.

Sarclisa® (isatuximab): The FDA approved Sanofi Aventis USA's intravenous antibody drug, Sarclisa®, in combination with pomalidomide and dexamethasone (pom-dex), for adults with multiple myeloma (cancer of the bone marrow) who have already undergone lenalidomide and protease inhibitor therapies. Qualifying patients include those whose disease has returned or become resistant to prior treatments. While in trial, Sarclisa® in combination with pom-dex showed a significant improvement in progression-free survival (PFS) with a median PFS of 11.53 months compared to 6.47 months taking pom-dex alone. Estimated cost per infusion for the average patient is $5,200 prior to insurance or patient assistance programs.

ISTURISA® (osilodrostat): The FDA granted Novartis Pharmaceuticals Inc. approval for ISTURISA®, a bi-daily oral tablet administered for the treatment of Cushing's disease, a condition caused by the overexposure of cortisol, a stress hormone produced by the adrenal glands, in adults who either cannot undergo pituitary gland surgery or have undergone surgery but still suffer from the disease. ISTURISA® is the first FDA-approved drug to directly address the disease by blocking a key enzyme used by the body to produce cortisol. In a trial conducted by Novartis, 86% of patients who received ISTURISA® for 32 weeks maintained cortisol levels within normal limits. Launch date and cost to be determined.

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KEY PIPELINE DRUGS WITH FDA APPROVAL DECISIONS EXPECTED BY THE END OF THE 2ND QUARTER 2020			
DRUG NAME	MANUFACTURER	INDICATION/ USE	EXPECTED FDA DECISION DATE
Fenfluramine	Zogenix	Dravet syndrome (a type of epilepsy with prolonged seizures that are often triggered by hot temperatures/ fever)	3/25/2020
Opicapone	Neurocrine Biosciences	Parkinson's Disease (a disorder of the central nervous system that affects movement)	4/24/2020
Dasotraline	Sunovion Pharmaceuticals	Binge Eating Disorder	5/14/2020
Risdiplam	Genentech/ Roche	Spinal muscular atrophy (a disorder characterized by weakness in muscles used for movement due to motor neuron degeneration)	5/22/2020
Amphora (L-lactic acid, citric acid, potassium bitartrate)	Evofem Biosciences	Prevention of Pregnancy	5/25/2020
Pemigatinib	Incyte	Cholangiocarcinoma (cancer of the tubes that carry the digestive fluid, bile, through the liver)	5/30/2020
Viltolarsen	Nippon Shinyaku	Duchenne muscular dystrophy (progressive weakness and loss of skeletal & heart muscles)	Jun-20
Obeticholic acid	Intercept Pharmaceuticals	Nonalcoholic steatohepatitis (liver inflammation/ damage caused by a buildup of fat in the liver)	6/26/2020
Selumetinib	AstraZeneca/ Merck	Neurofibromatosis (a genetic disorder of the nervous system that causes tumors to grow on nerves)	Quarter 2 2020

Resources

https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals

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https://www.bioworld.com/articles/433255-lundbecks-newly-approved-vyepti-enters-a-growth-market-for-migraine-prevention

SS&C Health 1st Quarter Pipeline Report

ON YOUR TEAM.