New drug information

- **Zulresso™ (brexanolone) injection, for intravenous use:** Sage Therapeutics received Food and Drug Administration (FDA) approval for Zulresso to treat postpartum depression (PPD). Zulresso is administered as a continuous intravenous infusion over 60 hours by a health care provider that must be available onsite to continuously monitor the patients. The prescribing information contains a Boxed Warning noting risk of excessive sedation or sudden loss of consciousness during administration and requires that patients be accompanied during interactions with their children. In clinical trials, Zulresso was administered one time to PPD patients who were then followed for four weeks. Zulresso is only available through a restricted program. Sage plans to price Zulresso at $34,000 per treatment course.  

- **Sunosi™ (solriamfetol):** Jazz Pharmaceuticals received FDA approval for Sunosi, an oral once daily medication to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea. Sunosi may not launch until it receives controlled substance scheduling. Jazz also manufacturers Xyrem® (sodium oxybate), an oral solution for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients seven years of age and older with narcolepsy. Xyrem is anticipated to be available generically in 2023.

- **Jatenzo® (testosterone undecanoate):** The FDA approved Clarus Therapeutics' Jatenzo, an oral androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone, such as primary hypogonadism or hypogonadotropic hypogonadism. Of note, it is not approved for age-related hypogonadal conditions which are not caused by structural or genetic etiologies. Jatenzo has a Boxed Warning noting increases in blood pressure. Jatenzo will compete for market share with Actient Pharmaceuticals oral buccal system, Striant, and topical testosterone products such as AbbVie's AndroGel® (testosterone gel) and Allergan's Androderm® (testosterone transdermal system). Clarus plans to launch Jatenzo before the end of 2019.

- **Efavirenz, lamivudine, and tenofovir disoproxil fumarate™:** AB Pharmaceuticals received FDA approval for Efavirenz, lamivudine, and tenofovir disoproxil fumarate 400 mg/300 mg/300 mg, a once daily triple drug combination for the treatment of HIV-1 infection in adult and pediatric patients weighing at least 35 kg. This combination contains the same medications and strengths as Mylan’s Symfi Lo®. This medication was reviewed under the President’s Emergency Plan for AIDS Relief (PEPFAR). Launch plans are pending.
● **Duaklir® Pressair® (aclidinium bromide and formoterol fumarate):** Circassia Pharmaceuticals received FDA approval for Duaklir for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Duaklir combines formoterol, a long-acting beta₂-adrenergic agonist (LABA), with aclidinium bromide, a long-acting muscarinic antagonist (LAMA) in one dry powder inhaler to be taken twice daily. Circassia expects to launch Duaklir in the second half of 2019.

● **Zelnorm® (tegaserod):** The FDA approved the reintroduction of Sloan Pharma/US WorldMeds' twice-daily oral Zelnorm for the treatment of adult women less than 65 years of age with irritable bowel syndrome with constipation (IBS-C). Zelnorm was voluntarily pulled from the U.S. market in 2007 by Novartis, the previous manufacturer, due to potential cardiac-related side effects. Since that time, Zelnorm was available only through an FDA-authorized expanded access program. Contraindications and Warnings/Precautions include the possible cardiovascular ischemic events and note the potential risks of treatment must be balanced with expectations of improvements in symptoms of IBS-C. Launch plans are pending.

● **Avaclyr™ (acyclovir ophthalmic ointment 3%):** Fera Pharmaceuticals' received FDA approval for Avaclyr for the topical ophthalmic treatment of acute herpetic keratitis (dendritic ulcers) in patients with herpes simple (HSV-1 and HSV-2) virus. Acyclovir is also available as a buccal tablet, oral capsule, oral suspension, oral tablet, injectable solution and topical cream and ointment. Oral and topical antivirals for the treatment of acute herpetic keratitis are considered equally effective. Launch plans are pending.

● **Welchol® (colesevelam hydrochloride) chewable bars, for oral use:** Daiichi Sankyo received FDA approval for Welchol in a chewable bar formulation for the same cholesterol/type 2 diabetes mellitus indications as other formulations. Welchol is also available as a brand name drug and generically in oral tablets and suspension. Launch plans are pending.

● **Dovato™ (dolutegravir and lamivudine):** The FDA approved Viiv Healthcare's Dovato, a complete once daily, single-tablet, two-drug regimen for the treatment of HIV-1 infection in adults with no antiretroviral treatment history and with no known substitutions associated with resistance to the individual components. Clinical trials found Dovato to have similar efficacy to a dolutegravir-based, three-drug regimen. The annual WAC of Dovato is $27,500.

● **Corlanor® (ivabradine):** Amgen received FDA approval for the oral solution formulation of Corlanor for the treatment of stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients ages 6 months and older. Prior to this approval, Corlanor was available only as tablets to reduce the risk of hospitalization for worsening heart failure in adult patients with stable, symptomatic chronic heart failure with reduced left ventricular ejection fraction.
Generic drug information

- **EryPed 400® (erythromycin ethylsuccinate):** Ani Pharmaceuticals launched the first generic for Arbor Pharmaceuticals’ EryPed 400 oral suspension for the treatment of certain infections. Other generic manufacturers are anticipated to launch their generic versions in October 2019.

- **Mestinon® (pyridostigmine bromide):** Novitium Pharma launched the first generic for Bausch Health’s Mestinon syrup for the treatment of myasthenia gravis. Novitium’s 180-day exclusivity ends in September 2019; however, no other manufacturers have approved abbreviated new drug applications (ANDAs). Mystinon syrup generated $10 million in U.S. annual sales in 2018.

- **Tekturna® (aliskiren):** Par/Endo launched the first generic for Noden Pharma’s Tekturna for the treatment of hypertension. No other generic manufacturers are anticipated to launch their generic versions at this time. U.S. annual sales in 2018 were $49 million.

- **Exjade® (deferasirox):** Actavis/Teva launched the first generic for Novartis’ Exjade for the treatment of chronic iron overload due to blood transfusions in certain patients. At least two other generic manufacturers are anticipated to launch their generic version of Exjade in October 2019. U.S. annual sales were $134 million in 2018.

- **Letairis® (ambrisentan):** Sun, Zydus, Par/Endo, and Sigmapharm have launched their generic versions of Gilead Sciences’ Letairis for the treatment of pulmonary arterial hypertension (PAH):  
  1. to improve exercise ability and delay clinical worsening, and  
  2. in combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability.

Multiple other manufacturers are expected to launch their generic versions in the second quarter of 2019. U.S. annual sales of Letairis in 2018 were $943 million.

*Specialty medication

References


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