New drug information

- **Xhance™ (fluticasone propionate) nasal spray**: OptiNose US, Inc received U.S. Food and Drug Administration (FDA) approval for Xhance for the treatment of nasal polyps in patients 18 years of age or older. Xhance is a nasal spray that is delivered into the nose by actuating the pump spray into one nostril while simultaneously blowing into the mouthpiece of the device.

- **Solosec™ (secnidazole oral granules)**: The FDA approved Symbiomix Therapeutics’ Solosec for the treatment of bacterial vaginosis. Secnidazole is the first single-dose oral treatment for bacterial vaginosis. A dose of secnidazole comes in the form of a 2-gram packet of granules that must be sprinkled onto applesauce, yogurt or pudding and consumed once within 30 minutes without chewing or crunching the granules.

- **Fiasp® (insulin aspart injection)**: The FDA approved Novo Nordisk’s Fiasp for the treatment of glycemic control in adults with type 1 and type 2 diabetes. Fiasp is a new formulation of Novo Nordisk’s NovoLog® with the addition of niacinamide (vitamin B3) which helps to increase the speed of the initial insulin absorption. The onset of appearance in the blood is approximately 2.5 minutes. Fiasp will launch at the same list price as NovoLog.¹

- **Bydureon® BCise™ (exenatide extended-release injectable suspension)**: AzstraZeneca announced the FDA-approved Bydureon BCise, a new formulation of Bydureon in an improved once-weekly, single-dose autoinjector device for adults with type 2 diabetes whose blood sugar remains uncontrolled on one or more oral medicines in addition to diet and exercise to improve glycemic control. Bydureon BCise is designed for ease and patient convenience in a once-weekly, pre-filled device with a pre-attached hidden needle. The medication is administered in three steps—mix, unlock, inject. Prior to this approval, Bydureon was available in a Pen in which the needle needed to be attached and that may have to be tapped 80 times to mix well before use. The Bydureon Pen will continue to be available; Bydureon BCise will launch in first quarter 2018.²
New generics

- **Lexiva® (fosamprenavir):** Mylan launched the first generic for Viiv Healthcare's Lexiva tablets for the treatment of HIV-1 infection in combination with other antiretroviral agents. Lupin is anticipated to launch their generic Lexiva product in June 2018.

- **Brisdelle® (paroxetine mesylate):** Solco Healthcare launched the first generic for Sebela Pharmaceuticals’ Brisdelle for the treatment of moderate to severe vasomotor symptoms associated with menopause (VMS). Actavis/Teva may launch their generic Brisdelle product in fourth quarter 2017.

- **Buphenyl® (sodium phenylbutyrate):** Par Pharmaceutical’s launched the first generic for Horizon Pharma’s Buphenyl for the adjunctive therapy in the chronic management of patients with urea cycle disorders.

- **Ziagen® (abacavir solution):** Camber Pharmaceuticals launched the first generic for Viiv Healthcare’s Ziagen solution. Other manufacturers of generic Ziagen are set to launch in August 2019.

- **Copaxone® (glatiramer acetate 40 mg/mL, injection):** Mylan launched the first generic for Teva Neuroscience’s Copaxone 40 mg/mL for the treatment of patients with relapsing forms of multiple sclerosis. Mylan may be eligible for 180-day exclusivity, but the FDA has not made a formal decision. According to IMS, Copaxone 40 mg had approximately $3.64 billion in U.S. annual sales.

- **Testim® 1% (testosterone gel):** Actavis Pharma launched the first generic for Endo Pharmaceutical’s Testim gel for the treatment of testosterone replacement in men.

References


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