Drug Pipeline Monthly Update

Critical updates in an ever changing environment

January 2018

New drug information

- **Steglatro™ (ertugliflozin):** The Food and Drug Administration (FDA) approved Merck & Co. and Pfizer’s Steglatro as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. Steglatro is the fourth sodium glucose co-transporter 2 (SGLT2) inhibitor approved by the FDA. Steglatro is approved as monotherapy and in the following combination products:

  - Steglujan™ (ertugliflozin/sitagliptin)
  - Segluromet™ (ertugliflozin/metformin)

- **Xepi™ (ozenoxacin) 1% cream:** The FDA approved Medimetriks’ Xepi for the topical treatment of impetigo due to Staphylococcus aureus or Streptococcus pyogenes in adult and pediatric patients 2 months of age and older. Xepi cream is to be applied topically to the affected area twice daily for 5 days. Patients as young as 2 months of age may use Xepi. Medimetriks plans to launch in first quarter of 2018.¹

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New generics

- **Sustiva® (efavirenz) capsules**: Rising Pharmaceuticals launched their generic version of BMS' Sustiva 50 mg and 200 mg capsules for the treatment of HIV. Other manufacturers are not expected to launch their generic versions until 2019.

- **Palgic® (carboxinamide maleate)**: Foxland Pharmaceuticals launched their generic version of Alfasigma USA's Palgic to relieve symptoms of allergy, hay fever, and the common cold.

- **Reyataz® (atazanavir)**: Teva launched their generic version of BMS' Reyataz for the treatment of HIV. Teva has 180-day exclusivity. Multiple manufacturers are set to launch their generic versions of Reyataz on June 26, 2018. According to IMS data as of October 2017, Reyataz had annual U.S. sales of $402 million.

- **Estrace® vaginal cream (estradiol vaginal cream, USP, 0.01%)**: Mylan launched their generic version of Allergan's Estrace Cream for moderate to severe symptoms of vulvar and vaginal atrophy due to menopause. Teva launched an authorized generic version of Estrace Cream. Two other manufacturers may launch their generic versions during 2018 or 2019. Estrace Cream had U.S. annual sales of $426 million according to IMS data as of August 2017.

References


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