PRIME THERAPEUTICS®

Drug Pipeline MONTHLY UPDATE

Critical updates in an ever changing environment

August 2021

NEW DRUG INFORMATION

- **Twyneo® (benzoyl peroxide and tretinoin):** The U.S. Food and Drug Administration (FDA) has approved Sol-Gel Technologies' Twyneo® (benzoyl peroxide and tretinoin) for the treatment of acne vulgaris in adults and pediatric patients nine years of age and older. Twyneo is a once-daily non antibiotic topical cream of a fixed-dose combination of benzoyl peroxide (3%) and tretinoin (0.1%). Twyneo was approved via the 505(b)2 pathway using benzoyl peroxide and Bausch Health's Retin-A® (tretinoin) as reference products. Twyneo conducted two Phase 3 clinical trials that demonstrated a statistically significant absolute change from baseline in inflammation. Results from Trial 1 showed that 39.9% of patients treated with Twyneo achieved investigator's global assessment (IGA) treatment success compared with 14.3% in the vehicle group. Findings from Trial 2 showed 26.8% of patients treated with Twyneo achieved IGA treatment success versus 15.1% in the vehicle group.[1] Twyneo is expected to launch shortly with pricing to follow.

GENERIC DRUG INFORMATION

- **Feraheme® (ferumoxytol):** Sandoz launched their generic version of AMAG Pharmaceuticals' Feraheme for the treatment of iron deficiency anemia in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron, or who have chronic kidney disease. Feraheme generated $562 million in U.S. annual sales in 2020.
- **Semglee® (insulin glargine-yfgn):** The FDA approved the first interchangeable biosimilar insulin product, indicated to improve glycemic control in adults and pediatric patients with Type 1 diabetes mellitus and in adults with Type 2 diabetes mellitus. Semglee (insulin glargine-yfgn) is both biosimilar to, and interchangeable with (can be substituted for), its reference product Lantus® (insulin glargine), a long-acting insulin analog. Semglee launched last year, prior to receiving this interchangeability designation.

- **Duexis® (ibuprofen/famotidine):** Alkem Laboratories launched their generic version of Horizon Therapeutics' Duexis as a combination of a nonsteroidal anti-inflammatory drug (NSAID) ibuprofen and the histamine H2-receptor antagonist famotidine. Duexis is indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers, which in the clinical trials was defined as a gastric and/or duodenal ulcer, in patients who are taking ibuprofen for those indications. The clinical trials primarily enrolled patients less than 65 years of age without a prior history of gastrointestinal ulcer. Controlled trials do not extend beyond 6 months. Duexis is an "at risk" launch due to ongoing litigation. Duexis generated $855 million in U.S. annual sales in 2020.
- **Atropine prefilled syringe injection, 0.25mg/5mL:** Accord Healthcare has launched their generic version of Hospira's atropine prefilled syringe for temporary blockade of severe or life-threatening muscarinic effects. Atropine prefilled syringe generated less than 10 million in U.S. annual sales in 2020.

REFERENCES

1. https://www.globenewswire.com/news-release/2021/07/27/2269561/0/en/Sol-Gel-Technologies-Announces-FDA-Approval-of-TWYNEO.html