PRIME THERAPEUTICS®

Drug Pipeline MONTHLY UPDATE

Critical updates in an ever-changing environment

January 2021

NEW DRUG INFORMATION

- **Klisyri™ (tirbanibulin):** The United States Food and Drug Administration (FDA) has approved tirbanibulin 1% ointment by Athenex for the topical treatment of actinic keratosis (AK) on the face and scalp. Klisyri is a first-in-class dual Src Kinase and tubulin polymerization inhibitor. In two Phase 3 clinical trials, Klisyri once daily for five days resulted in higher overall complete AK clearance rates at Day 57 than vehicle (44% vs 5%: 54% vs 13%, respectively).[1] Klisyri is supplied in boxes of five single-use sachets. It will launch first quarter of 2021 with pricing to follow.

- **Gemtesa™ (vibegron):** Sumitomo Pharmaceuticals' Gemtesa was approved by the FDA for treatment of overactive bladder (OAB), including patients with symptoms of urge urinary incontinence, urgency, and urinary frequency. Gemtesa is a 75mg once-daily tablet, beta-3 adrenergic agonist. Gemtesa was approved based on Phase 3, EMPOWUR trial, which demonstrated a statistically significant mean change from baseline (-1.8 micturitions for Gemtesa, -1.3 micturitions placebo, and -1.6 micturitions for tolterodine).[2] Gemtesa is currently in clinical trials seeking other indications, including in patients with pain associated with irritable bowel syndrome (IBS), in men with OAB with an enlarged prostate, and benign prostatic hyperplasia (BPH). Gemtesa has launched with average wholesale price (AWP) of $550 per 30 days.

- **Tlando™ (testosterone):** Lipocine's Tlando has been tentatively approved by the FDA, as an oral twice daily fixed dose, testosterone replacement therapy in adult males indicated for conditions associated with a deficiency or absence of endogenous testosterone: primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired). In granting tentative approval, the FDA has concluded that Tlando has met all required quality, safety and efficacy standards necessary for approval; but Tlando has not received final approval and is not eligible for final approval and marketing in the U.S. until the expiration of the exclusivity period previously granted to Clarus Therapeutics, Inc. with respect to Jatenzo®, which expires on March 27, 2022.[3] Tlando was approved based on an open-label, single-treatment, Phase 3 trial that demonstrated 80% of patients achieved average testosterone levels within the normal range when compared to baseline. Tlando will be waiting to launch in 2022 as declared by the FDA, with pricing to follow.

- **Verquvo™ (vericiguat):** The FDA has approved Verquvo for the reduction of risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for HF or need for outpatient intravenous (IV) diuretics in adults with symptomatic chronic heart failure and ejection fraction less than 45%. Verquvo is a soluble guanylate cyclase (sGC) stimulator that will be available as a 2.5mg, 5mg and 10mg tablet. It is the first treatment specifically for patients following a hospitalization for heart failure or need for outpatient IV diuretics that analysts predict will likely be saved for last-line treatment in sicker patients.[4] Verquvo's approval was based on the Phase 3 VICTORIA trial, that demonstrated a 10% relative risk reduction in composite cardiovascular-related death and heart failure hospitalization when compared to placebo.[5] The trial met its primary endpoint by demonstrating it was superior to placebo, in combination with other heart failure therapies; however, was mainly driven by re-hospitalization improvement without a clear benefit to cardiovascular death. Additionally, the VICTORIA trial showed there was a 4.2% reduction in annualized absolute risk with Verquvo compared with placebo. Verquvo is entering a market where Novartis' Entresto® (sacubitril/valsartan) is establishing itself as the new standard of care. Verquvo will be available in the coming weeks with pricing to follow.

GENERIC DRUG INFORMATION

- **Zytiga® (abiraterone)+:** Amneal launched their generic version of Janssen's Zytiga 500mg for the treatment of prostate cancer. Zytiga generated $577 million in U.S. annual sales in 2019.
- **Vivlodex® (meloxicam):** Lupin launched their generic version of Egalet's Vivlodex for the treatment of osteoarthritis pain. Multiple manufacturers are set to launch in the distant future. Vivlodex generated $14 million in U.S. annual sales in 2019.
- **Glucagon Emergency Kit® (glucagon (rdna) for injection kit):** Amphastar has launched their generic version of Lilly's Glucagon Emergency Kit for treatment of severe hypoglycemia. Mylan's generic is under active review set for later this year. Glucagon Emergency Kit generated $177 million in U.S. annual sales in 2019.
- **Naprelan® CR (naproxen CR):** Alovogen launched their generic version of Almatica's Naprelan CR for treatment of inflammation such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, tendinitis, bursitis, acute gout, primary dysmenorrhea, for the relief of mild to moderate pain. Naprelan CR generated less than $10 million in U.S. annual sales in 2019.

+Specialty medication **January 2021**

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