PRIME THERAPEUTICS®

Drug Pipeline MONTHLY UPDATE

Critical updates in an ever-changing environment

April 2021

NEW DRUG INFORMATION

- **Zegalogue™ (dasiglucagon HypoPal Rescue):** The U.S. Food and Drug Administration (FDA) approved Zealand Pharma's Zegalogue for injection for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged six years and above. Zegalogue was approved based on results from three Phase 3 studies with demonstrated time to plasma glucose recovery or treatment success as the primary endpoint. Zegalogue successfully achieved its primary endpoint for both adult and pediatric patients with a statistically significant faster median time to blood glucose recovery compared to placebo (10 minutes with Zegalogue administration compared to 30-45 minutes with placebo). In the main Phase 3 adult trial, 99% of patients recovered within 15 minutes.[1] Zegalogue will be sold as both an auto-injector (similar to Pfizer's EpiPen™) and a prefilled syringe.[2] Zegalogue has launched with an average wholesale price (AWP) of $370.80 per pen/syringe.

- **Roszet™ (ezetimibe and rosuvastatin):** Althera Pharmaceuticals' Roszet has been approved by the FDA as an adjunct to diet in patients with primary non-familial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C) and alone or as an adjunct to other LDL-C-lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C. Roszet is a once daily combination tablet. Roszet demonstrated a 72% reduction in LDL-C with the 40mg/10mg dose and a reduction of 64% with 10mg/10mg dose.[3] Roszet has launched with an AWP of $300 per 30 days.

- **Myrbetriq® Granules (mirabegron for extended-release oral suspension):** The FDA approved Astellas' Myrbetriq Granules for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients. This is indicated for patients aged three years and older. NDO is a type of bladder dysfunction caused by nerve damage and is marked by uncontrolled bladder contractions that can lead to symptoms of urinary frequency, urgency and incontinence. Myrbetriq Granules are first-in-class FDA-approved for children with NDO. Previous treatment options for NDO have been limited or invasive, including scheduled toileting, catheterization, or surgery. If left untreated, NDO can lead to the deterioration of urinary tract function at an early age. Myrbetriq Granules were approved based on a Phase 3 open-label study that demonstrated significant improvements in maximum cystometric capacity at week 24 (72.09 mL for ages three to 12 and 113.21 mL for ages 12 to 18).[4] Improvements were also observed on several secondary endpoints, including the number of overactive detrusor contractions, volume of urine held until first detrusor contraction, and number of daily urine leakage episodes.[4] Myrbetriq Granules are set to launch before the end of 2021 with pricing to follow.

- **Qelbree™ (viloxazine extended-release capsules):** Supernus' Qelbree was approved by the FDA for the treatment of attention-deficit hyperactivity disorder (ADHD) in pediatric patients six to 17 years of age. Qelbree is a non-stimulant capsule that can be opened and sprinkled on applesauce or swallowed whole. Phase 3 data demonstrated that Qelbree significantly improved patients' results on the ADHD Investigator Symptom Rating Scale (AISRS) compared to placebo. At the end of six weeks, those in the Qelbree group saw an improvement of -15.5 from baseline in AISRS scores compared to -11.7 in the placebo arm, which was statistically significant.[5] Qelbree will be seeking an additional indication for adult ADHD patients the second half of 2021. Qelbree has launched with an AWP of $11.96 per capsule.
- **Nextstellis™ (drospirenone and estetrol):** The FDA approved Mayne Pharma's Nextstellis for use by females of reproductive potential to prevent pregnancy. Nextstellis is a progestin and estrogen combination that has 3mg of drospirenone (DRSP) and 14.2mg of estetrol (E4). E4, a naturally occurring estrogen, produced from a plant source, has a unique mechanism of action with selective activity in tissues, focusing on those needed to support contraceptive efficacy and cycle control. Nextstellis approval was based on two Phase 3 clinical trials with 3,725 women, that demonstrated treatment with Nextstellis was safe, effective, and demonstrated cycle control, bleeding control, and tolerability.[6] Nextstellis met its primary end point, measured by the number of on-treatment pregnancies per 100 women per 12 months (0.45 for women 18-35 years of age, 0.28 for overall population).[6] Nextstellis will be available by the end of June 2021 with pricing to follow.

GENERIC DRUG INFORMATION

- **Azopt® (brinzolamide ophth susp, 1%):** Watson/Teva launched their generic version of Novartis' Azopt for the treatment of ocular hypertension or open-angle glaucoma. Azopt generated $196 million in U.S. annual sales in 2020.
- **Lyrica CR® (pregabalin ER tabs):** Multiple manufacturers have launched their generic version of Pfizer's Lyrica CR for treatment of neuropathic pain associated with diabetic peripheral neuropathy (DPN) and postherpetic neuralgia. Lyrica CR generated less than $10 million in U.S. annual sales in 2020.

+ Specialty medication

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