PRIME THERAPEUTICS®

Drug Pipeline MONTHLY UPDATE

Critical updates in an ever changing environment

October 2021

NEW DRUG INFORMATION

- **Qulipta™ (atogepant):** The U.S. Food and Drug Administration (FDA) has approved AbbVie's Qulipta for the preventive treatment of episodic migraine in adults. Qulipta was approved based on the Phase 3 ADVANCE study that demonstrated statistically significant reductions in mean monthly migraine days compared to placebo. Patients treated with 60mg of Qulipta across 12 weeks experienced a 4.2-day reduction from baseline compared with placebo that had a 2.5-day reduction.[1] Qulipta is available in a once-daily dose of 10mg, 30mg and 60mg. Qulipta has launched with a wholesale acquisition cost (WAC) of $990.90 per 30 days.

- **Tyrvaya® (varenicline nasal spray):** Oyster Point Pharma's Tyrvaya has been approved by the FDA as a 0.03mg nasal spray for the treatment of the signs and symptoms of dry eye disease. Tyrvaya nasal spray is the first nasal spray approved for the treatment of dry eye disease; it is administered twice daily. Tyrvaya binds to cholinergic receptors to activate the trigeminal parasympathetic pathway resulting in increased production of basal tear film as a treatment for dry eye disease. Tyrvaya was approved via the 505(b)2 pathway using Pfizer's Chantix® (varenicline) as its reference product. Tyrvaya demonstrated in two clinical trials that approximately half of patients (52%) who received Tyrvaya had increased tear production, compared to 14% and 28% of subjects in the control groups.[2] Tyrvaya is scheduled to launch in November 2021 with pricing to follow.

- **Zimhi® (naloxone pre-filled syringe):** Adamis Pharmaceuticals' Zimhi has been approved by the FDA for the treatment of opioid overdose. Zimhi is a high-dose naloxone injection 5mg/0.5mL that can be administered outside the care of a health care provider. Zimhi was approved via the 505(b)2 pathway using Adapt Pharma's Narcan (naloxone) as a reference product. According to statistics published by the Centers for Disease Control and Prevention (CDC), drug overdoses resulted in approximately 96,779 deaths in the United States during the 12-month period ending March 2021. This was a 29% increase over the prior 12-month period.[3] Zimhi is scheduled to launch first quarter of 2022 with pricing to follow.

GENERIC DRUG INFORMATION

- **Afinitor®+ (everolimus):** Multiple manufacturers have launched their generic versions of Novartis' Afinitor for treatment of advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib. Afinitor is also indicated for treatment of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS) that require therapeutic intervention but are not candidates for curative surgical resection. Four additional manufacturers are set to launch by the end of 2021. Afinitor generated $456 million in U.S. annual sales in 2020.
- **Afinitor Disperz®+ (everolimus tablets for oral suspension):** Mylan/Viatris has launched its generic version of Novartis' Afinitor Disperz for treatment of postmenopausal women with advanced hormone receptor-positive, HER2¬ negative breast cancer in combination with exemestane after failure of treatment with letrozole or anastrozole. Mylan is eligible for 180-day exclusivity. Afinitor Disperz generated $129 million in U.S. annual sales in 2020.

REFERENCES

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2. https://www.ophthalmologytimes.com/view/oyster-point-pharma-reports-fda-approval-tyrvaya-nasal-spray-for-ded
3. https://www.sec.gov/Archives/edgar/data/887247/000138713121010061/ex99-1.htm