PRIME THERAPEUTICS®

Drug Pipeline MONTHLY UPDATE

Critical updates in an ever changing environment

November 2021

NEW DRUG INFORMATION

- **Seglentis™ (tramadol 44mg and celecoxib 56mg tablet):** The U.S. Food and Drug Administration (FDA) has approved Esteve Pharmaceuticals and Kowa Pharmaceuticals America's fixed-dose co-crystal formulation of the opioid and the NSAID for management of acute pain in adults, specifically pain that is severe enough to require an opioid and for which alternative treatments are inadequate. Seglentis' approval was based on a Phase 3 trial that evaluated the efficacy and safety of Seglentis with acute postoperative pain after unilateral first metatarsal osteotomy with internal fixation compared to placebo. It was approved via the 505(b)(2) pathway using Pfizer's Celebrex® (celecoxib) and Janssen Pharmaceuticals' Ultram® (tramadol) as reference products.[1] As it contains tramadol, Seglentis is classified as a Schedule IV controlled substance. Seglentis is supplied as a coated tablet containing 56mg of celecoxib and 44mg of tramadol hydrochloride in 30- and 90-count bottles. The product is expected to be available in early 2022 with pricing to follow.
- **Vuity™ (pilocarpine HCl ophthalmic solution):** The FDA approved Allergan's Vuity 1.25% for the treatment of presbyopia, commonly known as age-related blurry near vision, in adults. Vuity is the first FDA-approved eye drop to treat this common and progressive eye condition that affects 128 million Americans, nearly half of the U.S. adult population. Vuity is an optimized eye drop formulation of the cholinergic muscarinic receptor agonist that is administered once-daily. Vuity's application is supported by the Phase 3 study, GEMINI 1, that demonstrated patients who received Vuity versus the vehicle reported clinically meaningful and statistically significant greater improvement in ability and satisfaction related to near vision reading as well as reduction in use of presbyopia coping mechanisms. Vuity treated patients increased the ability to read three additional lines on a reading chart in low light, high contrast, binocular Distance Corrected Near Visual Acuity (DCNVA) at day 30, hour 3 (22.5%) and hour 6 (9.7%) versus the vehicle.[2] Vuity had a rapid onset of action of 15 minutes and duration of up to six hours in low light DCNVA without loss of distance vision after administration at Day 30. Vuity has launched with an average wholesale price (AWP) of $88.20 per 2.5mL bottle.

- **Eprontia™ (topiramate) oral solution, 25mg/mL:** The FDA has approved Azurity Pharmaceuticals' Eprontia as the first liquid formulation of topiramate as a monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients two years of age and older; an adjunctive therapy for treatment of partial-onset seizures, primary generalized tonic-clonic seizures or seizures associated with Lennox-Gastaut syndrome in patients two years of age and older; and, as a preventive treatment of migraine in patients 12 years of age and older.[3] Eprontia was approved via the 505(b)(2) pathway using Janssen's Topamax® (topiramate) as its reference product. Eprontia has launched with an AWP of $797 per bottle (473mL).

GENERIC DRUG INFORMATION

- **Zomig® nasal spray 5mg/spray:** Padagis/Perrigo has launched its version of AstraZeneca's Zomig nasal spray indicated for the acute treatment of migraine with or without aura in adults. Zomig nasal spray 5mg/spray generated $62 million in U.S. annual sales in 2020.

REFERENCES

1. https://www.pharmacytimes.com/view/fda-approves-seglentis-for-acute-pain-management
2. https://www.prnewswire.com/news-releases/us-food-and-drug-administration-approves-vuity-pilocarpine-hci-ophthalmic-solution-1-25-the-first-and-only-eye-drop-to-treat-presbyopia-age-related-blurry-near-vision-301412259.html
3. https://www.prnewswire.com/news-releases/azurity-pharmaceuticals-inc-announces-fda-approval-of-eprontia-topiramate-oral-solution-301417993.html