PRIME THERAPEUTICS®

Drug Pipeline MONTHLY UPDATE

Critical updates in an ever-changing environment

August 2020

NEW DRUG INFORMATION

- **Breztri™ Aerosphere (budesonide/glycopyrronium/formoterol fumarate):** The U.S. Food and Drug Administration (FDA) approved AstraZeneca's Breztri for the treatment of chronic obstructive pulmonary disease (COPD). Breztri Aerosphere is a fixed dose triple-combination of budesonide, glycopyrrolate, and formoterol fumarate in a metered-dose inhaler (MDI). Approval of Breztri comes from the Phase 3 ETHOS trial that demonstrated a statistically significant reduction in the rate of moderate or severe exacerbations compared with two dual-combination therapies in patients with moderate to very severe chronic COPD. Compared with AstraZeneca's Bevespi® Aerosphere (glycopyrronium/fomoterol fumarate), Breztri Aerosphere achieved a 24% reduction in exacerbations and a 13% reduction compared to AstraZeneca's Symbicort® (budesonide/formoterol fumarate). The secondary endpoint for Breztri Aerosphere showed a 46% reduction in the risk of all-cause mortality compared with Bevespi Aerosphere. AstraZeneca has launched Breztri with a wholesale acquisition cost (WAC) of $590 per 10.7g inhaler or approximately $7,080 a year.[1]

- **Xeglyze™ (abametapir):** The FDA approved Hatchtech's Xeglyze for treatment of head lice infestation for ages six months of age and older. Xeglyze is a metalloproteinase inhibitor with ovicidal and lousicidal activity formulated as a 0.74% lotion that is applied in a single 10-minute application. Xeglyze has been approved based on two clinical trials where patients were evaluated on days one, seven, and 14. In both studies, the proportion of index patients free of live lice at all visits was 81% with Xeglyze, compared to 50% with vehicle.[2] Xeglyze launch and pricing are pending.

- **Olinvyk™ (oliceridine):** Trevena's Olinvyk has been approved by the FDA for the management of moderate-to-severe acute pain in the hospital or a similar setting. Olinvyk is a G-protein ligand that targets the mu opioid receptor, in which Trevena claims a reduced incidence of opioid-related adverse events, like nausea and hypoventilation, when compared with IV morphine. However, the FDA approved Olinvyk under the same regulatory umbrella as traditional opioids, stating the safety profile was similar to other opioids. The FDA emphasized strict limits with Olinvyk, stating, "Of note, this particular medication is only indicated for use in a controlled clinical setting, meaning under medical supervision and not for use in a take-home prescription."[3] Olinvyk's approval was based on results from Phase 3 studies that demonstrated rapid analgesic efficacy when compared to placebo.[4] Olinvyk does not have active metabolites and therefore does not require dosage adjustments in patients with renal impairments compared to morphine. Unlike other opioids for intravenous administration, Olinvyk

injection has a maximum recommended daily dose limit of 27mg. Trevena hopes to expand the use of Olinvyk in the broader context than how it was studied. Olinvyk is expected to be available in the fourth quarter of 2020 after the U.S. Drug Enforcement Administration (DEA) issues its controlled substance schedule. Pricing will follow.

- **Lampit™ (nifurtimox):** The FDA granted accelerated approval of Bayer's Lampit for use in pediatric patients (from birth to less than 18 years of age; weight at least 2.5kg) for the treatment of Chagas disease (American trypanosomiasis) caused by trypanosoma cruzi. Chagas is an infectious tropical disease that affects an estimated 300,000 people in the United States. Bayer designed the antiprotozoal as a dispersible, dividable tablet that provides a greater range and accuracy to dosing. Approval of Lampit was based on a Phase 3 safety and efficacy trial that compared the 60-day or 30-day Lampit treatment regimen. The Lampit 60-day regimen showed superiority. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. Lampit launch and price are pending.[5]

GENERIC DRUG INFORMATION

- **Demser® (metyrosine capsule):** Amneal Pharmaceuticals has launched their generic version of Bausch Health's Demser for the treatment of pheochromocytoma. Demser generated $14 million in U.S. annual sales in 2019. Demser is not protected by any patents or regulatory exclusivities.
- **Jadenu Sprinkle® (deferasirox oral granules)+:** Ascend Laboratories has launched their generic version of Novartis' Jadenu Sprinkle for the treatment of chronic iron overload due to blood transfusion. Jadenu Sprinkle generated $25 million in U.S. annual sales in 2019. There are no longer any patents listed for Jadenu Sprinkle.
- **Ciprodex® (ciprofloxacin/dexamethasone otic susp):** Dr. Reddy's has launched their generic version of Alcon/Novartis' Ciprodex for the treatment of acute otitis externa or otitis media. Ciprodex generated $496 million in U.S. annual sales in 2019. Multiple manufacturers are set to launch 2020.
- **Protonix® for oral suspension (pantoprazole DR for oral susp):** Sun Pharmaceuticals has launched their generic version of Pfizer's Protonix for oral suspension for the treatment of gastroesophageal reflux disease (GERD). Protonix for oral suspension generated $47 million in U.S. annual sales in 2019.

+ Specialty medication

REFERENCES

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