PRIME THERAPEUTICS®

Drug Pipeline MONTHLY UPDATE

Critical updates in an ever-changing environment

February 2020

NEW DRUG INFORMATION

- **Dificid® (fidaxomicin):** The U.S. Food and Drug Administration (FDA) approved Merck's Dificid oral suspension for the treatment of Clostridium difficile-associated diarrhea (CDAD) ages six months and older. Dificid is a macrolide antibacterial that is only used to treat infections that are proven or strongly suspected to be caused by *Clostridioides difficile (C. difficile)* for resistance purposes. Previously Merck's Dificid tablets (fidaxomicin) were only approved for the treatment of C. difficile-associated diarrhea in adults aged older than 18 years. The FDA also expanded Dificid tablet's indication to include six months of age and older. Dificid's approval was based on a Phase 3 trial that evaluated 148 patients less than 18 years of age receiving Dificid or vancomycin. Clinical responses after 10 days of treatment were similar (77.6% Dificid vs 70.5% vancomycin). The overall sustained response at 30 days post-treatment was 68.4% and 50.0% respectively.[1] Dificid's launch and price are pending.

- **Monoferric™ (ferric derisomaltose):** Pharmacosmos' Monoferric has been approved by the FDA as an IV iron replacement product for treatment of iron deficiency anemia (IDA) in adults who are intolerant or responded unsatisfactorily to oral iron or who have non-hemodialysis dependent chronic kidney disease (NDD-CKD). Monoferric is a 100 mg/mL, single-dose injection that is infused over at least 20 minutes. It allows for infusion of 1000 mg of iron in one visit. The FDA's approval was based on two clinical trials. Trial 1, Ferwon-IDA, included patients with IDA who had intolerance to oral iron or who had unsatisfactory response to oral iron or for whom there was a clinical need for rapid repletion of iron stores. Trial 2, Ferwon-nephro, included patients with IDA who had non-dialysis dependent chronic kidney disease. Both trials measured mean change in hemoglobin from baseline to week 8 and met primary endpoints.[2] Launch and pricing pending.

- **Arazlo™ (tazarotene):** The FDA approved Ortho Dermatologics' Arazlo for the treatment of acne vulgaris ages nine and up. Arazlo is a low dose concentration lotion intended to decrease adverse reactions commonly associated with Tazarotene such as skin irritation and dryness. The FDA approved Arazlo based on two phase 3 clinical trials that demonstrated its tolerability and met its primary endpoint of success on the Evaluator's Global Severity Score (EGSS) assessed at week 12. Additionally, in a phase 2 head to head comparative study, Arazlo lotion showed similar efficacy compared to Taro Pharmaceuticals' Tazorac® (tazarotene 0.1% cream) with fewer side effects (5.6% Tazorac vs 2.9% Arazlo).[3] Arazlo will be available in a 45-gram tube. Ortho Dermatologic expects to launch Arazlo in the first half of 2020 with pricing to follow.

- **Trijardy XR™ (empagliflozin, linagliptin and metformin XR):** Boehringer Ingelheim and Eli Lilly's Trijardy XR has been approved by the FDA for treatment of type 2 diabetes. Trijardy XR provides three type 2 diabetes medicines in one tablet. The FDA approved Trijardy XR based on two randomized trials that found bioequivalence of empagliflozin, linagliptin and metformin extended release fixed dose combination tablets to their individual components in healthy adults. The safety profile of Trijardy XR was found to be consistent with its individual components.[4] Trijardy XR will be available in four fixed dosages. Trijardy XR price and launch pending.
- **Pizensy™ (lactitol):** The FDA approved Braintree Laboratories' Pizensy for the treatment of chronic idiopathic constipation (CIC) in adults. Pizensy, an osmotic laxative, is dosed at 20 grams orally, once daily. The FDA approved Pizensy based on three clinical trials that demonstrated complete spontaneous bowel movements change from baseline during short-term treatments of less than four weeks.[5] Launch and pricing are pending.

GENERIC DRUG INFORMATION

- **Zohydro ER® (hydrocodone bitartrate ER 12-hour abuse-deterrent capsules):** Alvogen launched their generic version of Currax Pharmaceuticals' Zohydro ER for the treatment of pain. No exclusivities remain for Zohydro ER. Zohydro ER generated $42 million in U.S. annual sales in 2018.
- **K-tab® (potassium chloride ER):** Multiple manufacturers are set to launch their generic version of Abbvie's K-tab for the treatment of hypokalemia. There are no patents or regulatory exclusivities remaining for K-tab. K-tab generated $25 million in U.S. annual sales in 2018.
- **Moxeza® (moxifloxacin ophth soln):** Multiple manufacturers are set to launch their generic version of Novartis' Moxeza for the treatment of bacterial conjunctivitis. Lupin holds a 180-day exclusivity on generic Moxeza. Moxeza generated $10 million in U.S. annual sales in 2018.

REFERENCES

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