

Drug Pipeline MONTHLY UPDATE

Critical updates in an ever changing environment

May 2020

NEW DRUG INFORMATION

- **Ongentys™ (opicapone):** The U.S. Food and Drug Administration (FDA) approved Neurocrine Biosciences' Ongentys in combination with levodopa/carbidopa to treat patients with Parkinson's disease experiencing OFF episodes. Patients who have Parkinson's disease taking levodopa/carbidopa may begin to experience "off" time between treatment doses which cause motor symptoms such as tremors, slowed movements and difficulty walking to occur. Ongentys protects levodopa by reducing its breakdown in the blood, making more levodopa available to reach the brain, prolonging its clinical effects and helping patients achieve motor symptom control and increases "on" time without troublesome dyskinesia. Unlike other COMT inhibitors Ongentys is dosed once daily and not limited by liver toxicity. Ongentys' FDA approval was based on data from 38 clinical studies with more than 1,000 Parkinson's disease patients. BIPARK1 and BIPARK2, Ongentys' Phase 3 clinical trials, demonstrated that Ongentys 50mg significantly reduced "off" time from baseline to week 14 or 15 compared to placebo. "On" time without troublesome dyskinesia also increased from baseline to week 14 or 15 compared to placebo.¹ Neurocrine Biosciences plans to delay launch of Ongentys to later this year due to COVID-19. A Neurocrine Biosciences representative stated the company priced the drug "below the specialty tier" at approximately \$670 per month.²
- **Milprosa™ (progesterone):** Ferring Pharmaceuticals' Milprosa has been approved by the FDA to support embryo implantation and early pregnancy (up to 10 weeks post-embryo transfer) by supplementation of corpus luteal function as part of an Assisted Reproductive Technology (ART) treatment program for infertile women up to and including 34 years of age. The FDA-approved Milprosa, based on a study that demonstrated clinically recognized pregnancy rate, defined as the presence of at least one fetal heartbeat seen on ultrasound at 6- and 10-weeks post embryo transfer, compared with active comparator. Milprosa was non-inferior to active comparator with a clinical pregnancy rate of 48% at 6 weeks (percentage difference vs. active comparator: 0.8; 95% CI: -4.6, 6.3) and 46.4% at 10 weeks post-embryo transfer (percentage difference vs. active comparator: 1.3; 95% CI: -4.1, 6.7).³ Ferring Pharmaceuticals launch and pricing for Milprosa are pending.

GENERIC DRUG INFORMATION

- **Adrenalin® Injection (epinephrine injection):** Multiple manufacturers have launched their generic versions of Par/Endo's Adrenalin injection for the treatment of anaphylactic reactions. Adrenalin Injection generated \$168 million in U.S. annual sales in 2019.
- **Jadenu® (deferasirox):** Teva has launched their generic version of Novartis' Jadenu 180mg tablet for the treatment of chronic iron overload from blood transfusions. Multiple manufacturers have launched their versions of Jadenu 90mg and 360mg in 2019. Jadenu generated \$421 million in U.S. annual sales in 2019.

REFERENCES

1. <https://www.prnewswire.com/news-releases/neurocrine-biosciences-announces-fda-approval-of-once-daily-ongentys-opicapone-as-an-add-on-treatment-for-patients-with-parkinsons-disease-experiencing-off-episodes-301047469.html>
2. <https://www.fiercepharma.com/pharma/neurocrine-scores-fda-nod-for-parkinson-s-drug-ongentys-but-won-t-launch-amid-pandemic>
3. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/201110s000lbl.pdf

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