

# Drug Pipeline MONTHLY UPDATE

Critical updates in an ever changing environment

October 2020

## NEW DRUG INFORMATION

- **Alkindi™ Sprinkle (hydrocortisone granules):** The U.S. Food and Drug Administration (FDA) approved Eton Pharmaceuticals' Alkindi Sprinkle for the treatment of adrenocortical insufficiency, specifically designed for use in infants, children and adolescents from birth to < 17 years old. Eton Pharmaceuticals estimates that pediatric adrenocortical insufficiency affects between 5,000 and 11,000 children in the United States.<sup>1</sup> Alkindi Sprinkle is a glucocorticoid receptor agonist that was approved via the 505(b)(2) pathway using Pfizer's Cortef® (hydrocortisone) as its reference drug.<sup>2</sup> Alkindi Sprinkle is formulated as taste-neutral granules that can be sprinkled on food. Alkindi Sprinkle will be available in 0.5 mg, 1 mg, 2 mg, and 5 mg strengths, allowing clinicians greater flexibility to individualize dosing based on each patient's needs in accordance with the instructions for dosage and administration. Eton Pharmaceuticals will commercialize Alkindi Sprinkle in the U.S. with a launch in the fourth quarter of 2020 and pricing to follow.

## GENERIC DRUG INFORMATION

- **Bethkis® (tobramycin neb soln):**<sup>+</sup> Teva launched its generic version of Chiesi USA's Bethkis for the treatment of cystic fibrosis. Bethkis generated \$42 million in U.S. annual sales in 2019.
- **Ferriprox® (deferiprone tablet):**<sup>+</sup> Taro launched its generic version of Chiesi USA's Ferriprox for the treatment of chronic iron overload. Taro has 180-day exclusivity with one manufacture set to launch in 2021. Ferriprox generated less than \$10 million in U.S. annual sales in 2019.
- **Tecfidera Starter Pack® (dimethyl fumarate DR cap starter pack):**<sup>+</sup> Cipla launched its generic version of Biogen's Tecfidera Starter pack for the treatment of relapsing multiple sclerosis. Tecfidera Starter pack U.S. annual sales in 2019 are unknown.
- **Atripla® (disoproxil, fumarate and efavirenz/emtricitabine/tenofovir):** Teva has launched its generic version of Gilead's Atripla for the treatment of HIV. Multiple manufacturers are set to launch March 2021. Atripla has generated \$732 million in U.S. annual sales in 2019.
- **Truvada® (emtricitabine/tenofovir disoproxil fumarate):** Teva has launched its generic version of Gilead's Truvada for the treatment of HIV. Multiple manufacturers are set to launch March 2021. Truvada has generated \$4.104 billion in U.S. annual sales in 2019.

- **Tykerb® (lapatinib):**<sup>+</sup> Lupin Pharmaceuticals has launched its generic version of Novartis's Tykerb for the treatment of HER2-positive breast cancer. Tykerb generated \$67 million in U.S. annual sales in 2019.
- **Monurol® (fosfomycin granules for oral soln):** Xiromed has launched its generic version of Zambon's Monurol for the treatment of urinary tract infection. Monurol generated \$32 million in U.S. annual sales in 2019.
- **Aptensio XR® (methylphenidate ER 24hr):** Actavis/Teva has launched its generic version of Rhodes' Aptensio XR for the treatment of attention deficit hyperactivity disorder. Aptensio XR generated \$40 million in U.S. annual sales in 2019.
- **Kerydin® (tavaborole topical soln 5%):** Encube Ethicals has launched its generic version of Sandoz's Kerydin for the topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* (fungal infections). Multiple manufacturers are set to launch 180 days later. Kerydin generated \$81 million in U.S. annual sales in 2019.

<sup>+</sup>Specialty medication

## REFERENCES

1. <https://www.globenewswire.com/news-release/2020/03/27/2007542/0/en/Eton-Pharmaceuticals-Announces-Acquisition-of-U-S-Marketing-Rights-to-Pediatric-Orphan-Drug-Alkindi-Sprinkle.html>
2. <https://www.globenewswire.com/news-release/2020/09/29/2101010/0/en/Eton-Pharmaceuticals-Announces-FDA-Approval-of-Orphan-Drug-ALKINDI-SPRINKLE-hydrocortisone-as-Replacement-Therapy-in-Pediatric-Patients-with-Adrenocortical-Insufficiency.html>

*All brand names are property of their respective owners.*