

# Drug Pipeline MONTHLY UPDATE

Critical updates in an ever changing environment

July 2021

## NEW DRUG INFORMATION

- **Soanz™ (torsemide):** The U.S. Food and Drug Administration (FDA) has approved Sarfez Pharmaceuticals' Soanz (torsemide) for a once-a-day improved formulation of the loop diuretic torsemide. Soanz is an alternative for patients suffering from heart failure who experience persistent edema, swelling in the lower limbs and/or abdomen, despite a loop diuretic therapy.<sup>1</sup> Soanz has a longer duration of peak effects compared with similar loop diuretics without causing excessive urination. Soanz launch and price are pending.
- **Astepro® Allergy (azelastine) Nasal Spray:** The FDA approved Astepro Allergy (azelastine HCl 0.15%) as an over-the-counter (OTC) product for the temporary relief of nasal congestion, runny nose, sneezing and itchy nose due to hay fever or other upper respiratory allergies. With the FDA's approval, Astepro Allergy becomes the first and only steroid free, antihistamine nasal spray for allergies available OTC in the United States for adults and children six years of age and older. Currently, OTC allergy medications includes three major classes: antihistamines, intranasal steroids and mast cell stabilizers.<sup>2</sup> Astepro Allergy will be the first and only OTC antihistamine nasal spray for indoor and outdoor allergy relief upon the OTC switch. Astepro Allergy OTC will launch first quarter of next year.
- **Verkazia™ (cyclosporine ophthalmic emulsion):** The FDA has approved Verkazia (cyclosporine ophthalmic emulsion) 0.1% eye drops for the treatment of vernal keratoconjunctivitis (VKC) in children and adults. Verkazia was approved via the 505(b)2 pathway using Allergan's Restasis® (cyclosporine ophthalmic emulsion) as its reference product.<sup>3</sup> Verkazia's launch and price are pending.
- **Kerendia™ (finerenone):** The FDA has approved Bayer Pharmaceutical's Kerendia to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease associated with type 2 diabetes (T2D). Kerendia is a nonsteroidal mineralocorticoid receptor antagonist. Kerendia was approved based on a Phase 3 clinical trial FIDELIO-DKD, which demonstrated positive kidney and cardiovascular outcomes compared to placebo. Kerendia reduced the incidence of the primary composite endpoint of a sustained decline in eGFR of ≥40%, kidney failure, or renal death. The event rate (100 patient year) was 7.6 and 9.1 for Kerendia and placebo, respectfully. The treatment effect reflected a reduction in a sustained decline in eGFR of ≥40% and progression to kidney failure.<sup>4</sup> Kerendia has launched and is available as a 10mg and 20mg tablet. Kerendia's average wholesale price (AWP) is \$683 per 30-day supply.

- **fexinidazole:** The FDA has approved Sanofi's fexinidazole as the first all-oral treatment for both stages of the *Trypanosoma brucei gambiense*, a form of sleeping sickness (Human African trypanosomiasis) in patients six years of age and older and weighing at least 20 kg. Sleeping sickness is a parasitic disease transmitted by the bite of an infected tse-tse fly. It affects mostly populations living in remote rural areas of sub-Saharan Africa, where about 65 million people are at risk of infection. Left untreated, sleeping sickness is almost always fatal.<sup>5</sup> Sanofi plans to provide the drug free-of-charge to the World Health Organization (WHO) for distribution to affected countries, as part of a long-term collaboration with WHO.

## GENERIC DRUG INFORMATION

- **Intence® (etravirine tab, 100mg, 200mg):** Amneal Pharmaceuticals launched its generic version of Janssen Products' Intence for the treatment of HIV-1 infection. Intence generated \$126 million in U.S. annual sales in 2020.
- **Brovana® (arformoterol neb soln, 15mcg/2 mL):** Slate Run Pharmaceuticals launched its generic version of Sunovion Pharmaceuticals' Brovana for the treatment of chronic obstructive pulmonary disease (COPD). Brovana generated \$438 million in U.S. annual sales in 2020.
- **Perforomist® (formoterol neb soln 20mcg/2 mL):** Teva launched its generic version of Mylan Specialty's Perforomist for the long-term, twice daily (morning and evening) administration in the maintenance treatment of bronchoconstriction in patients with COPD, including chronic bronchitis and emphysema. Perforomist generated \$367 million in U.S. annual sales in 2020.
- **Argatroban® (argatroban injection 50mg/mL):** Sagent Pharmaceutical launched its generic version of Hikma's Argatroban for prophylaxis or treatment of thrombosis in adult patients with heparin-induced thrombocytopenia (HIT) or as an anticoagulant in adult patients with, or at risk for, HIT undergoing percutaneous coronary intervention (PCI). Argatroban generated less than \$10 million in U.S. annual sales in 2020.

+ Specialty medication

## REFERENCES

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2. <https://www.fiercepharma.com/pharma/no-more-prescriptions-bayer-turns-allergies-drug-over-counter-fda-nod-for-astepro>
3. <https://www.businesswire.com/news/home/20210624005365/en/Santen-Receives-FDA-Approval-for-Verkazia%E2%84%A2-Cyclosporine-Ophthalmic-Emulsion-0.1-for-the-Treatment-of-Vernal-Keratoconjunctivitis-in-Children-and-Adults>
4. <https://www.businesswire.com/news/home/20210709005441/en/Bayer%E2%80%99s-KERENDIA%C2%AE-finerenone-Receives-U.S.-FDA-Approval-for-Treatment-of-Patients-with-Chronic-Kidney-Disease-Associated-with-Type-2-Diabetes>
5. <https://www.sanofi.com/en/media-room/press-releases/2021/2021-07-19-07-30-00-2264542>

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