Drug Pipeline **MONTHLY UPDATE**

Critical updates in an ever changing environment

JANUARY 2022

NEW DRUG INFORMATION

- **Dartisla ODT™ (glycopyrrolate):** The U.S. Food and Drug Administration (FDA) has approved Edenbridge's Dartisla ODT (glycopyrrolate) orally disintegrating tablets. Dartisla ODT is available in a 1.7mg orally disintegrating tablet and is indicated for adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer. It was approved via the 505(b)(2) pathway using Casper Pharma's Robinul® (glycopyrrolate) as its reference drug.[1] Glycopyrrolate is currently available generically as an oral tablet formulation for adjunctive therapy in the treatment of peptic ulcer. Dartisla ODT has launched with an average wholesale price (AWP) of $6.67 per tablet.

- **Rezvoglar™ (insulin glargine-aglr):** The FDA has approved Eli Lilly's Rezvoglar (insulin glargine-aglr) as a biosimilar to Sanofi's Lantus® (insulin glargine) to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. This is the second biosimilar approval for Lantus. Viatris/Biocon Biologics' Semglee® (insulin glargine-yfgn) was approved on July 28, 2021 as the first interchangeable biosimilar to Lantus.[2] Rezvoglar has not been granted interchangeable status; therefore, a patient would need a prescription from a health care prescriber written specifically for Rezvoglar. The FDA noted that biosimilars marketed in the U.S. typically have launched with initial list prices 15% to 35% lower than comparative list prices of reference products.[3] Rezvoglar launch and price are pending.

- **Apretude™ (cabotegravir extended-release injectable suspension):** The FDA has approved ViiV Healthcare's Apretude as the first long-acting injectable pre-exposure prophylaxis (PrEP) option to reduce the risk of sexually acquired HIV-1. Apretude is indicated for use in adults and adolescents weighing at least 35 kg who are at risk of sexually acquiring HIV and who have a negative HIV-1 test prior to initiation. Apretude is given first as two injections, one month apart, and then every two months thereafter. Apretude was approved based on two clinical trials that compared it to once daily oral Gilead Sciences' Truvada® (tenofovir disoproxil fumarate/ emtricitabine).

The first trial demonstrated that patients who took Apretude had 69% less risk of getting infected with HIV when compared to participants who took Truvada. The second trial demonstrated participants who took Apretude had 90% less risk of getting infected with HIV when compared to participants who took Truvada.[4] According to the Centers for Disease Control and Prevention, PrEP use in the United States is at approximately 25% of the 1.2 million people for whom it is recommended. This increase is up from about 3% usage in 2015.[5] Apretude has launched with a wholesale acquisition cost (WAC) of $3,700 per vial.

- **Quviviq™ (daridorexant):** Idorsia Pharmaceuticals' Quviviq has been approved by the FDA for the treatment of individuals with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. Quviviq is a dual orexin receptor antagonist, which blocks the binding of the wake-promoting neuropeptides orexins and is thought to turn down overactive wakefulness, as opposed to treatments that generally sedate the brain. Quviviq was approved based on a Phase 3 clinical trial which demonstrated significant improvement compared to placebo on objective measures of sleep onset, sleep maintenance, and patient reported total sleep time. Quviviq improved daytime functioning by 33.7% relative attribute importance [RAI) according to patients.[6] Quviviq is anticipated to be classified as a controlled substance. Quviviq is scheduled to launch May 2022 with pricing to follow.
- **Ryaltris™(mometasone and olopatadine) nasal spray:** The FDA approved Glenmark Pharmaceuticals' Ryaltris as a fixed-dose, combination drug product nasal spray for the treatment of symptoms of seasonal allergic rhinitis in adults and pediatric patients 12 years of age and older. Ryaltris was approved via the 505(b)(2) pathway using Alcon's Patanase® nasal spray (olopatadine hydrochloride) and Merck's Nasonex® (mometasone) as reference products.[7] Ryaltris launch and price are pending.

GENERIC DRUG INFORMATION

- **Cloderm® (clocortolone cream):** Taro launched its generic version of EPI Health's Cloderm for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. U.S. annual sales are unknown.
- **Narcan® (naloxone nasal spray, 4mg/0.1 mL):** Teva Pharmaceuticals launched its generic version of Adapt Pharma's Narcan for the treatment of opioid overdose. Narcan nasal spray generated $388 million in U.S. annual sales in 2021.
- **Cuvposa® (glycopyrrolate oral soln, 1mg/5 mL):** Par Pharmaceuticals launched its generic version of Merz Pharmaceuticals Cuvposa to reduce chronic severe drooling in patients aged 3-16 years with neurologic conditions associated with problem drooling (e.g., cerebral palsy). Cuvposa generated $26 million in U.S. annual sales in 2021.
- **Vasostrict® (vasopressin inj, 20unit/mL):** Eagle Pharmaceuticals has launched its generic version of Par's Vasostrict indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines. Eagle Pharmaceuticals has been granted 180-day marketing exclusivity. Vasostrict generated $786 million in U.S. annual sales in 2021.

+Specialty medication

REFERENCES

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