PRIME THERAPEUTICS®

Drug Pipeline MONTHLY UPDATE

Critical updates in an ever changing environment

July 2020

NEW DRUG INFORMATION

- **Semglee™ (insulin glargine):** The U.S. Food and Drug Administration (FDA) approved Sanofi's Semglee to improve glycemic control in adults with diabetes mellitus. Insulin glargine is a long-acting basal insulin analogue, administered once daily with a duration of 18 to 26 hours. Semglee was approved by the FDA under the 505(b)(2) pathway using Sanofi's Lantus® (insulin glargine) as its reference drug.[1] Semglee has been approved for all the same indications as Lantus. Semglee will be available in vial and prefilled pen form.
- **Lyumjev™ (insulin lispro-aabc):** The FDA approved Lilly's Lyumjev, a new rapid-acting insulin indicated to improve glycemic control in adults with type 1 and type 2 diabetes. Lyumjev is considered a novel formulation of insulin lispro, developed to speed the absorption of insulin into the blood stream and reduce A1C levels. Lyumjev was approved under a BLA (351(a)) application, therefore it is not considered a biosimilar or interchangeable with other available insulins.[2] Lyumjev will be available in a vial or as a prefilled pen. Lyumjev has launched with an average wholesale price (AWP) $330 per 10mL vial and AWP $127 per 100 unit/mL 3mL pen, $255 per 200 unit/mL per 3mL pen.
- **Gimoti™ (metoclopramide nasal spray):** Evoke Pharma's Gimoti has been approved by the FDA for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis. Gimoti is administered nasally, bypassing the diseased gastrointestinal track, allowing the drug to enter the bloodstream directly. Gimoti's approval was based off 505(b)(2) pathway using ANI Pharmaceuticals' Reglan® (metoclopramide) as its reference drug.[3] Janssen Pharmaceuticals withdrew its Propulsid® (cisapride) in 2000, leaving only ANI Pharmaceuticals Reglan® (metoclopramide) which has restrictive safety labeling. There are safety concerns with gastroparesis medications. Gimoti labeling includes a box warning for tardive dyskinesia, a risk for all formulations of metoclopramide, that limits use to no longer than 12 weeks. Evoke Pharma plans to launch fourth quarter 2020 with pricing to follow.

- **Rukobia™ (fostemsavir):** The FDA approved ViiV Healthcare's Rukobia in combination with other antiretrovirals for treatment of heavily treatment-experienced adults with multidrug-resistant HIV-1 infection, who are unable to form a suppressive regimen due to resistance, intolerance or safety considerations. It is the first in a new class called attachment inhibitors, which work by latching onto the gp120 protein on the surface of HIV and blocking the virus from entering and infected immune cells. Rukobia was approved based on the Phase 3 BRIGHTE study, which evaluated Rukobia compared with placebo over 96 weeks. Rukobia demonstrated superiority over placebo, which was measured by decline in HIV-1 RNA copies per mL (0.79 vs 0.17log10 copies/mL decline respectively). Sixty percent of individuals who received Rukobia on top of an investigator-selected background therapy achieved undetectable HIV viral load. Mean changes in CD4+ cell count from baseline continued to increase over the span of the trial.[4] Rukobia's launch and pricing are pending.
- **Byfavo™ (remimazolam):** The FDA approved Acacia Pharma's Byfavo as a very rapid onset/offset IV benzodiazepine sedative for use during invasive medical procedures lasting 30 minutes or less. Byfavo is ultra-short acting and reversible intravenous medication. The FDA approval was based on evidence from three clinical trials in adult patients undergoing short procedures, that measured success of procedures that required no alternative sedatives. Acacia plans to launch Byfavo in the second half of 2020 with pricing to follow.[5]
- **Upneeq™ (oxymetazoline ophthalmic solution 0.1%):** Osmotica Pharmaceuticals' Upneeq received FDA approval for the treatment of acquired blepharoptosis, or ptosis, a condition characterized by the abnormal drooping of the upper eyelid that can limit field of vision. Upneeq is the only FDA-approved pharmacotherapy treatment for ptosis. Upneeq was approved based on two clinical trials that demonstrated statistically significant improvements compared to placebo in both superior visual fields as measured by the Leicester Peripheral Field Test (LPFT) and eyelid lift, as measured by the Marginal Reflex Distance Test (MRD-1). Osmotica plans to make Upneeq commercially available by August 2020 to a selected group of ophthalmologists and optometrists with pricing to follow.[6]
- **Wynzora™ (calcipotriene 0.005% and betamethasone 0.064%) cream:** The FDA approved MC2 Therapeutics Wynzora for the topical treatment of plaque psoriasis in patients 18 years of age and older. Wynzora is a vitamin D3 receptor agonist fixed-dose combination of the D3 derivative and steroid formulated as a topical cream using MC2's PAD technology, which encapsulates and stabilizes the internal oil phase in a thin aqueous film of surfactants. Wynzora's approval was based on a Phase 3 clinical trial compared against active comparator Leo Pharma's Taclonex® Topical Suspension (calcipotriene and betamethasone dipropionate, w/w 0.005%/0.064%). Wynzora met its primary endpoint by demonstrating success at week eight by two-grade improvement on the physician global assessment (PGA) scale. The difference in PGA treatment success to the active comparator was 14.6% in favor of Wynzora cream.[7] Wynzora launch and price are pending.

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