Letybo (letibotulinumtoxinA-wlbg) – New drug approval

- On March 4, 2024, Hugel announced the FDA approval of Letybo (letibotulinumtoxinA-wlbg), for the temporary improvement in the appearance of moderate to severe glabellar (frown) lines associated with corrugator and/or procerus muscle activity in adult patients.

- Letybo is another botulinum toxin product.

- The efficacy of Letybo was established in three randomized, double-blind, placebo-controlled studies in 1,276 patients for temporary improvement of the appearance of moderate to severe glabellar facial lines. Patients were randomized to a single treatment with Letybo or placebo. The primary endpoint was measured at week 4 and was treatment success, defined as the proportion of patients achieving a score of 0 or 1 and an improvement of at least 2 points from baseline at maximum frown, as assessed independently by both the investigator and the patient using the Glabellar Line Scale.

    — Across the three studies, treatment success was achieved in 47% to 65% of patients with Letybo vs. 0% to 2% of patients with placebo.

- Letybo carries a boxed warning for distant spread of toxin effect.

- Letybo is contraindicated in:

    — Patients with known hypersensitivity to any botulinum toxin preparation or to any of the components in the Letybo formulation
    — The presence of infection at the proposed injection site(s).

- Warnings and precautions for Letybo include lack of interchangeability between botulinum toxin products; serious adverse reactions with unapproved use; hypersensitivity reactions; cardiovascular system adverse reactions; increased risk of clinically significant effects with pre-existing neuromuscular disorders; dysphagia and dyspnea; pre-existing conditions at the injection site; ophthalmic adverse reactions in patients treated with botulinum toxin products; and human albumin and transmission of viral diseases

- The most common adverse reaction with Letybo use was headache.

- The total recommended dose of Letybo is 20 Units per treatment session divided into five equal intramuscular injections of 4 Units each (two injections in each corrugator muscle and one injection in the procerus muscle).

    — Letybo should be administered no more frequently than every three months.

- Hugel plans to launch Letybo in the second half of 2024. Letybo will be available as a 50 Units or 100 Units powder in single-dose vials.