Daxxify™ (daxibotulinumtoxinA-lanm) – New drug approval

- On September 8, 2022, Revance Therapeutics announced the FDA approval of Daxxify (daxibotulinumtoxinA-lanm), for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.

- Other botulinum toxins approved for severe glabellar lines (frown lines) include Dysport® (abobotulinumtoxinA), Xeomin® (incobotulinumtoxinA), Botox® Cosmetic (onabotulinumtoxinA), and Jeuveau® (prabotulinumtoxinA-xvfs).

    — Other botulinum toxins, including those listed, are also approved for various non-cosmetic, therapeutic uses.

- The efficacy of Daxxify was established in a two randomized, double-blind, placebo-controlled studies (Studies GL-1 and GL-2) in 609 adult patients with moderate-to-severe glabellar lines. Efficacy was determined based on frown wrinkle severity at maximum frown using a 4-point scale (0 = none, 1 = mild, 2 = moderate, 3 = severe). The primary endpoint (treatment success) was defined as achieving a score of 0 or 1 (none or mild) and an improvement of at least 2 points from baseline for both the investigator's and subject's assessments at week 4.

    — Treatment success was achieved in 74% of patients treated with Daxxify in both studies vs. 0% of patients treated with placebo in both trials (treatment difference 74 in both studies, 95% CI: 68, 80).

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

- Daxxify is contraindicated:

    — In patients with known hypersensitivity to any botulinum toxin preparation, Daxxify or any of the components in the Daxxify formulation
    — In the presence of infection at the proposed injection sites.

- Additional warnings and precautions for Daxxify include lack of interchangeability between botulinum toxin products; serious adverse reactions with unapproved use; hypersensitivity reactions; cardiovascular system; pre-existing neuromuscular disorders; dysphagia and breathing difficulties; pre-existing conditions at the injection site; and ophthalmic adverse reactions.

- The most common adverse reactions (≥ 1%) with Daxxify use were headache, eyelid ptosis, and facial paresis.

- The total recommended dose of Daxxify is 40 Units per treatment session divided into five equal intramuscular injections of 8 Units each (two injections in each corrugator muscle and one injection in the procerus muscle). Daxxify should be administered no more frequently than every 3 months.

    — Refer to the Daxxify drug label for complete dosing and administration recommendations.

- Revance Therapeutics' launch plans for Daxxify are pending. Daxxify will be available as 50 Units or 100 Units sterile lyophilized powder in a single-dose vial.