Jeuveau™ (prabotulinumtoxinA-xvfs) – New drug approval

- On February 1, 2019, Evolus announced the FDA approval of Jeuveau (prabotulinumtoxinA-xvfs), for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.

- Jeuveau is a proprietary 900 kDa purified botulinum toxin type A formulation.

- The approval of Jeuveau was based on two identical, placebo-controlled studies evaluating Jeuveau use in the temporary improvement of the appearance of moderate to severe glabellar facial lines. The studies enrolled a total of 654 patients. The primary efficacy endpoint was measured at day 30 and was defined as the proportion of patients achieving ≥ 2-grade improvement from baseline at maximum frown, as assessed using the Glabellar Line Scale (GLS). The GLS is a 4-point grading scale (0 = none, 1 = mild, 2 = moderate, 3 = severe).

    — In studies 1 and 2, 67% and 71% of patients receiving Jeuveau, respectively, achieved the primary endpoint vs. 1% of patients receiving placebo in both studies.

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

- Jeuveau is contraindicated in patients with hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation and infection at the injection site.

- Additional warnings and precautions of Jeuveau include lack of interchangeability between botulinum toxin products; serious adverse reactions with unapproved use; hypersensitivity reactions; cardiovascular system adverse events; increased risk of clinically significant effects with pre-existing neuromuscular disorders; and dysphagia and breathing difficulties.

- The most commonly reported adverse reactions with Jeuveau use include headache (9.3%), eyelid ptosis (2%), upper respiratory tract infection (3%), and increased white blood cell count (1%).

- The recommended dose of Jeuveau for glabellar line administration is 0.1 mL (4 units) by intramuscular injection into each of five sites, for a total dose of 20 units.

    — Retreatment of Jeuveau should be administered no more frequently than every three months.
    — Consideration of the cumulative dose is necessary when treating adult patients with Jeuveau for glabellar lines if other botulinum toxin products are or have been used to treat other indications approved for those products.
    — Jeuveau is not interchangeable with other preparations of botulinum toxin products.

- Evolus plans to launch Jeuveau in the spring of 2019. Jeuveau will be available as a vacuum-dried powder supplied in a single-dose vial (100 units).

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