Xeomin® (incobotulinumtoxinA) – Expanded indication

- On May 14, 2019, Merz Pharmaceuticals announced the FDA approval of Xeomin (incobotulinumtoxinA), for the treatment of blepharospasm in adult patients.
    - Xeomin was previously approved for the treatment of adults with blepharospasm who were previously treated with onabotulinumtoxinA (Botox®).
- Xeomin is also approved for the treatment of chronic sialorrhea, upper limb spasticity, cervical dystonia, and glabellar lines.
- Blepharospasm causes muscles around the eyes to contract involuntarily. Patients suffering from blepharospasm can experience symptoms including excessive blinking, light sensitivity, dry eyes, eye irritation, and watering eyes.
    - Blepharospasm affects up to 50,000 patients in the U.S.
- The efficacy of Xeomin for the treatment of blepharospasm in treatment-naïve patients was evaluated in a double-blind study in a total of 61 patients. During the placebo-controlled phase, a fixed total dose of 25 units Xeomin, 50 units Xeomin, or placebo was administered intramuscularly at 6 injection sites per eye. The primary efficacy variable was the change from baseline in Jankovic Rating Scale (JRS) severity subscore determined at week 6 after the injection.
    - The 50 unit treatment group demonstrated statistically significant improvements in the primary endpoint vs. placebo, with a difference of -1.2 ($p = 0.0004$). The change from baseline in the JRS severity subscore for the 25 unit treatment group was not statistically significant, with a difference of -0.5 ($p = 0.1452$) vs. placebo.
- Xeomin carries a boxed warning for distant spread of toxin effect.
- In treatment-naïve patients, the recommended initial dose of Xeomin for treatment of blepharospasm is 50 units (25 units per eye). In patients previously treated with a botulinum toxin A, their past dose, response to treatment, duration of effect, and adverse event history should be taken into consideration when determining the Xeomin dose.
    - The total dose of Xeomin should not exceed 100 units per treatment session (50 units per eye).
    - Xeomin is injected into the lateral and medial orbicularis oculi muscle of the upper lid; lateral canthus and the lateral orbicularis oculi muscle of the lower lid; and the corrugator muscle, if necessary. The number and location of injections may be changed in response to adverse reactions or based on the patient's response to treatment.
    - The frequency of Xeomin repeat treatments should be determined by clinical response but should generally be no more frequent than every 12 weeks.
    - Refer to the Xeomin drug label for dosing for all its other indications.