Xeomin® (incobotulinumtoxinA) – Expanded indication

- On December 18, 2020, the FDA approved Merz Pharmaceuticals' Xeomin (incobotulinumtoxinA), for the treatment of chronic sialorrhea in patients 2 years of age and older.
    - Xeomin was previously approved for this indication in adult patients only.
- Xeomin is also approved for:
    - Treatment of upper limb spasticity in adult patients.
    - Treatment of upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy.
    - Treatment of cervical dystonia in adult patients.
    - Treatment of blepharospasm in adult patients.
    - Temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.
- The approval of Xeomin for the expanded indication was based on a randomized, double-blind, placebo-controlled study in 216 pediatric patients 6 to 17 years of age with chronic sialorrhea. An additional 35 patients 2 to 5 years of age were treated with open-label Xeomin in the study. The primary efficacy analysis was conducted in the 6 to 17 years of age patient group. The co-primary endpoints were the change in unstimulated Salivary Flow Rate (uSFR) and carer's Global Impression of Change Scale (GICS) at week 4 post-injection.
    - At week 4, the mean change in uSFR (g/min) from baseline to week 4 was -0.14 and -0.07 for patients treated with Xeomin and placebo, respectively ($p = 0.0012$).
    - At week 4, mean carer's GICS at week 4 was 0.91 and 0.63 for patients treated with Xeomin and placebo, respectively ($p = 0.0320$).
    - Efficacy in pediatric patients 2 to 5 years of age is extrapolated from the finding of efficacy in older pediatric patients.
- Xeomin carries a boxed warning for distant spread of toxin effect.
- In pediatric patients with chronic sialorrhea, Xeomin is injected into the parotid and submandibular glands on both sides. Ultrasound imaging is recommended to guide needle placement into the salivary glands. The body-weight adjusted dose is divided with a ratio of 3:2 between the parotid and submandibular glands. The timing for repeat treatment should be determined based on the actual clinical need of the individual patient, and no sooner than every 16 weeks.
    - Xeomin has not been studied in children weighing less than 12 kg.
    - Refer to the Xeomin drug label for additional dosing and administration recommendations in chronic sialorrhea and for Xeomin's other indications.