Xeomin® (incobotulinumtoxinA) – Expanded indication

- On August 19, 2020, Merz announced the FDA approval of Xeomin (incobotulinumtoxinA), for the treatment or improvement of upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy.
    - Previously, Xeomin was approved for the treatment or improvement of upper limb spasticity in adults.
- Xeomin is also approved for adults for the treatment or improvement of chronic sialorrhea, cervical dystonia, blepharospasm, and temporary improvement in the appearance of moderate to severe glabellar lines with corrugator and/or procerus muscle activity.
- The approval for Xeomin for the expanded indication was based on a double-blind study enrolling 350 pediatric patients 2 to 17 years of age with upper limb spasticity in one or both upper limbs. Patients were randomized to one of three dosages of Xeomin: 2 units/kg, 6 units/kg or 8 units/kg. The 2 units/kg dose served as the control. The co-primary efficacy variables were the change from baseline on the Ashworth Scale for the primary clinical target pattern (ie, elbow flexors or wrist flexors), and the Investigator's Global Impression of Change Scale (GICS), both at week 4.
    - At week 4, the mean change in the Ashworth Scale for the Xeomin 2 units/kg group was -0.9 vs. -1.2 for the 8 units/kg group (Least square [LS] mean difference: 0.22; 95% CI: -0.40, -0.04; $p < 0.05$).
    - The GICS was 1.6 for the Xeomin 2 units/kg group vs. 1.7 for the 8 units/kg group (LS mean difference: 0.09; 95% CI: -0.10, 0.28).
    - There was no significant difference in change from baseline in Ashworth Scale score or the GICS score for the Xeomin 6 units/kg group vs.the 2 units/kg group.
- Xeomin carries a boxed warning for distant spread of toxin effect including swallowing and breathing difficulties.
- The most common adverse reactions (≥ 3%) with Xeomin use in pediatric patients with upper limb spasticity were nasopharyngitis and bronchitis.
- The exact dosage, frequency, and number of injection sites for Xeomin for the treatment of upper limb spasticity in pediatric patients should be tailored to the individual patient based on size, number and localization of involved muscles; the severity of spasticity; and the presence of local muscle weakness.
    - The maximum recommended dose of Xeomin is 8 units/kg, divided among affected muscles, up to a maximum dose of 200 units per single upper limb. If both upper limbs are treated, the total Xeomin dosage should not exceed 16 units/kg, up to a maximum of 400 units.
- Refer to the Xeomin drug label for further dosing recommendations and for dosing for all its other indications.