Dysport® (abobotulinumtoxinA) – Expanded indication

- On September 26, 2019, Ipsen Biopharmaceuticals announced the FDA approval of Dysport (abobotulinumtoxinA), for the treatment of upper limb spasticity in pediatric patients 2 years of age and older, excluding spasticity caused by cerebral palsy.
    - Dysport was previously approved for the treatment of lower limb spasticity in pediatric patients 2 years of age and older.
- Dysport is also approved for cervical dystonia in adults, glabellar lines in adults less than 65 years of age, and spasticity in adults.
- The approval of Dysport for the expanded indication was based on a double-blind, low-dose controlled study in 208 pediatric patients 2 years of age and older with upper limb spasticity. Patients received Dysport 16 units/kg, Dysport 8 units/kg, or Dysport 2 units/kg. The primary efficacy endpoint was the mean change from baseline in Modified Ashworth Score (MAS) in the primary targeted muscle group (PTMG) at week 6.
    - Dysport showed statistically significant improvements in the primary endpoint, with doses of 8 units/kg and 16 units/kg vs. the low dose Dysport (2 Units/kg) (-2.0, -2.3 and -1.6, respectively).
- Dysport carries a boxed warning for distant spread of toxin effect.
- The most common adverse reactions (≥ 10%) with Dysport use in pediatric patients with upper limb spasticity were upper respiratory tract infection and pharyngitis.
- The recommended dose of Dysport for the treatment of upper limb spasticity (excluding spasticity caused by cerebral palsy) in pediatric patients is 8 units/kg to 16 units/kg intramuscularly per limb. The maximum recommended total dose administered per treatment session must not exceed 16 units/kg or 640 units, whichever is lower.
- Refer to the Dysport drug label for complete dosing and administration recommendations for this indication and all its other indications.