Somatuline® Depot (lanreotide) – New indication

- On September 18, 2017, Ipsen announced the FDA approval of Somatuline Depot (lanreotide) 120 mg injection, for the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analogue rescue therapy.

- Somatuline Depot is also indicated for the long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy and the treatment of adult patients with unresectable, well- or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.

- The new indication was approved based on a 16-week, placebo-controlled trial in 115 patients with carcinoid syndrome. The primary efficacy outcome measure was the percentage of days in which patients administered at least one injection of rescue medication for symptom control.

    — Patients in the Somatuline Depot arm experienced 15% fewer days on rescue medication vs. patients in the placebo arm (34% vs. 49% of days, respectively; p = 0.02).

- The most common adverse events (≥ 5% and at least 5% > placebo) with Somatuline Depot use in patients with carcinoid syndrome were headache, dizziness and muscle spasm.

- The recommended dosage for Somatuline Depot for carcinoid syndrome is 120 mg administered every 4 weeks by deep subcutaneous injection.

    — If patients are already being treated with Somatuline Depot for GEP-NETs, an additional dose does not need to be administered for the treatment of carcinoid syndrome.
    — Somatuline Depot is intended for administration by a healthcare provider.
    — Consult Somatuline Depot's drug label for recommended doses for other indications.

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