Lanreotide injection – New drug approval

- On December 19, 2021, Cipla Limited announced the FDA approval of Lanreotide injection, for the:
    - Long-term treatment of acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. The goal of treatment in acromegaly is to reduce growth hormone (GH) and insulin growth factor-1 (IGF-1) levels to normal.
    - Treatment of adult patients with unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.

- Lanreotide injection was approved via the 505(b)(2) New Drug Application pathway and the active ingredient, route of administration and strengths are the same as Somatuline Depot®.
    - In addition to acromegaly and GEP-NETs, Somatuline Depot is also approved for the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

- Warnings and precautions for Lanreotide injection include cholelithiasis and complications of cholelithiasis; hyperglycemia and hypoglycemia; cardiovascular abnormalities; thyroid function abnormalities; and monitoring laboratory tests.

- The most common adverse reactions (> 5%) with Lanreotide injection use for acromegaly are diarrhea, cholelithiasis, abdominal pain, nausea, and injection site reactions.

- The most common adverse reactions (> 10%) with Lanreotide injection use for GEP-NET are abdominal pain, musculoskeletal pain, vomiting, headache, injection site reaction, hyperglycemia, hypertension, and cholelithiasis.

- The recommended starting dosage of Lanreotide Injection for acromegaly is 90 mg given via the deep subcutaneous (SC) route, at 4-week intervals for 3 months. After 3 months, the Lanreotide injection dosage may be adjusted as follows:
    - GH greater than 1 ng/mL to less than or equal to 2.5 ng/mL, IGF-1 normal, and clinical symptoms controlled: maintain dosage at 90 mg every 4 weeks
    - GH greater than 2.5 ng/mL, IGF-1 elevated, and/or clinical symptoms uncontrolled: increase dosage to 120 mg every 4 weeks
    - GH less than or equal to 1 ng/mL, IGF-1 normal, and clinical symptoms controlled: reduce dosage to 60 mg every 4 weeks
    - Thereafter, the dosage should be adjusted according to the response of the patient as judged by a reduction in serum GH and/or IGF-1 levels; and/or changes in symptoms of acromegaly.

- The recommended dosage of Lanreotide Injection for GEP-NET is 120 mg administered every 4 weeks by deep SC injection.

- Lanreotide injection is intended for administration by a healthcare provider.

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- Cipla’s launch plans for Lanreotide injection are pending. Lanreotide injection will be available as 60 mg/0.2 mL, 90 mg/0.3 mL, and 120 mg/0.5 mL single-dose prefilled syringes.

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