Signifor® LAR (pasireotide) – New indication

- On June 29, 2018, the FDA approved Novartis' Signifor LAR (pasireotide), for the treatment of patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.
    - Signifor LAR is also approved for the treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option.
- Pasireotide is also available as branded Signifor injection, which carries the same Cushing's disease indication as Signifor LAR. However, Signifor is not indicated for acromegaly.
- The safety and efficacy of Signifor LAR for Cushing's disease was studied in 150 patients who received two different dosages (10 mg and 30 mg) of Signifor LAR for 12 months. The primary endpoint was the proportion of patients in each arm who were mean urinary free cortisol (mUFC) responders (mUFC ≤ upper limit of normal) after 7 months of treatment.
    - The proportion of patients with mUFC response at month 7 was 39.2% (95% CI: 28.0, 51.2) in the 10 mg arm and 40.8% (95% CI: 29.7, 52.7) in the 30 mg arm. Both groups achieved the primary endpoint.
    - In addition, the responder rates at month 12 were 35.1% and 25.0% in the 10 mg and 30 mg starting dose groups, respectively.
- The recommended initial dosage of Signifor LAR for Cushing's disease is 10 mg by intramuscular (IM) injection once every four weeks.
    - Signifor LAR must be administered by a trained health care professional only by IM injection in the right or left gluteus immediately after reconstitution.
    - Prior to the initiation of Signifor LAR, it is recommended that patients have baseline evaluations for fasting plasma glucose and hemoglobin A1c, liver tests, electrocardiogram, serum potassium and serum magnesium levels.
    - Patients with poorly controlled diabetes mellitus who have inadequate glucose control should have anti-diabetic therapy optimized prior to starting Signifor LAR.
    - Consult the Signifor LAR drug label for acromegaly dosing recommendations.