Bynfezia® (octreotide acetate) – New drug approval

- On January 28, 2020, the FDA approved Sun Pharmaceutical's Bynfezia (octreotide acetate) pen, for the following indications:

    - To reduce blood levels of growth hormone and insulin-like growth factor 1 (somatomedin C) in adult patients with acromegaly who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses.
    - Treatment of adult patients with severe diarrhea and flushing episodes associated with metastatic carcinoid tumors.
    - Treatment of adult patients with the profuse watery diarrhea associated with vasoactive intestinal peptide-secreting tumors (VIPomas).
    - In patients with acromegaly, the effect of Bynfezia on improvement in clinical signs and symptoms, reduction in tumor size, and rate of growth has not been determined.
    - In patients with carcinoid syndrome and VIPomas, the effect of Bynfezia on the tumor size, rate of growth and development of metastases has not been determined.

- Octreotide acetate is also available generically as a solution for injection and as branded Sandostatin® LAR Depot powder for suspension for injection. These other formulations of octreotide share the same indications as Bynfezia.

- Warnings and precautions for Bynfezia include cholelithiasis and complications of cholelithiasis; hyperglycemia and hypoglycemia; thyroid function abnormalities; cardiac function abnormalities; and decreased vitamin B_{12} levels and abnormal Schilling's tests.

- The most common adverse reactions with Bynfezia use include:

    - Diarrhea, loose stools, nausea and abdominal discomfort in > 30% of patients with acromegaly and > 5% of patients with carcinoid tumors and VIPomas.
    - Gallstones and sinus bradycardia in > 25% in patients with acromegaly.

- The recommended initial dose of Bynfezia for the treatment of acromegaly is 50 mcg administered subcutaneously (SC) three times daily. The typical dosage is 100 mcg three times a day.

- The recommended dosage of Bynfezia for carcinoid tumors is 100 to 600 mcg daily in 2 to 4 divided doses during the first 2 weeks of therapy. The recommended dosage during the first 2 weeks of therapy for VIPomas ranges from 200 mcg daily to 300 mcg daily in 2 to 4 divided doses.

    - In clinical studies for carcinoid tumors, the median daily maintenance dosage was approximately 450 mcg, but clinical and biochemical benefits were obtained in some patients with as little as 50 mcg, while others required doses up to 1,500 mcg daily. Experience with doses above 750 mcg daily is limited.
    - For VIPomas, the dosage should be adjusted to achieve a therapeutic response; daily dosage is 150 mcg to 750 mcg but usually doses above 450 mcg daily are not required.

Continued . . .

- Sun Pharmaceuticals' launch plans for Bynfezia are pending. Bynfezia will be available as a 2,500 mcg/mL single-patient-use pen injection.