Ongentys® (opicapone) – New drug approval

- On April 27, 2020, Neurocrine Biosciences announced the FDA approval of Ongentys (opicapone), as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.

- PD is a chronic, neurodegenerative disorder that affects approximately one million people in the U.S. It is caused by low dopamine levels produced in the brain. The current standard for treatment of motor symptoms associated with PD is levodopa/carbidopa.

    - As the disease progresses, the beneficial effects of levodopa begin to wear off more quickly. Patients then experience motor fluctuations throughout the day between "on" time, periods when the medication is working and PD symptoms are controlled, and "off" time, when the medication is not working and motor symptoms return.

- Ongentys is a selective and reversible inhibitor of the catechol-O-methyltransferase (COMT) enzyme, which breaks down levodopa, making more levodopa available to reach the brain.

- The efficacy of Ongentys for the adjunctive treatment to levodopa/carbidopa in patients with PD experiencing "off" episodes was evaluated in two double-blind, randomized, placebo- and active-controlled studies. In study 1, 600 patients were randomized to treatment with one of 3 doses of Ongentys. In study 2, 427 patients were randomized to treatment with either one of two doses of Ongentys or placebo. The primary efficacy endpoint was the change in mean absolute OFF-time based on 24-hour patient diaries completed 3 days prior to each of the scheduled visits.

    - In both studies, Ongentys 50 mg significantly reduced mean absolute OFF-time vs. placebo. In study 1, the placebo-subtracted difference was -1.01 hours (95% CI: -1.620, -0.407; p = 0.002). In study 2, the placebo-subtracted difference was -0.91 hours (95% CI: -1.523, -0.287; p = 0.008).

- Ongentys is contraindicated in patients with:

    - Concomitant use of non-selective monoamine oxidase (MAO) inhibitors
    - Pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms

- Warnings and precautions for Ongentys include cardiovascular effects with concomitant use of drugs metabolized by COMT; falling asleep during activities of daily living and somnolence; hypotension/syncope; dyskinesia; hallucinations and psychosis; impulse control/compulsive disorders; and withdrawal-emergent hyperpyrexia and confusion.

- The most common adverse reactions (≥ 4% and > placebo) with Ongentys use were dyskinesia, constipation, increased blood creatine kinase, hypotension/syncope, and decreased weight.

- The recommended dose of Ongentys is 50 mg orally once daily at bedtime.

Continued . . .

- Neurocrine Biosciences plans to launch Ongentys later this year. Ongentys will be available as 25 mg and 50 mg capsules.