Onapgo™ (apomorphine) – New drug approval

- On February 4, 2025, Supernus Pharmaceuticals announced the FDA approval of Onapgo (apomorphine), for the **treatment of motor fluctuations in adults with advanced Parkinson's disease**.

- Onapgo is the first subcutaneous apomorphine infusion device.

- The efficacy of Onapgo was established in a randomized, double-blind, placebo-controlled study in 104 patients with Parkinson's disease who had motor fluctuations while receiving carbidopa/levodopa and other concomitant medications to treat Parkinson's disease. Patients were randomized to Onapgo or placebo. The primary endpoint was the change in total daily OFF time assessed from baseline to the end of the 12-week treatment period based on patient diaries.

    - The least squares mean change from baseline in OFF time was -0.90 ± 0.416 with placebo vs. -2.55 ± 0.487 (difference of -1.65, 95% CI: -2.91, -0.38, p = 0.0114).

- Onapgo is contraindicated in patients:

    - Using concomitant $5HT_3$ antagonists, including antiemetics (eg, ondansetron, granisetron, dolasetron, palonosetron) and alosetron.
    - With hypersensitivity/allergic reaction to apomorphine or any of the excipients of Onapgo, including sulfite (ie, sodium metabisulfite).

- Warnings and precautions for Onapgo include serious adverse reactions after intravenous administration; nausea and vomiting; falling asleep during activities of daily living and somnolence; syncope/hypotension/orthostatic hypotension; falls; infusion site reactions and infections; hallucinations/psychotic-like behavior; dyskinesia; hemolytic anemia; impulse control/compulsive behaviors; cardiac events; QTc prolongation and potential for proarrhythmic effects; hypersensitivity; fibrotic complications; priapism; and retinal pathology in albino rats.

- The most common adverse reactions (≥ 10% on Onapgo and at least twice the rate of placebo) with Onapgo use were infusion site nodule, nausea, somnolence, infusion site erythema, dyskinesia, headache, and insomnia.

- The recommended initial continuous dosage (continuous infusion) of Onapgo is 1 mg/hr. The dose should be titrated, as needed, in 0.5 mg/hr to 1 mg/hr increments. Patients in clinical studies used a mean of 4 mg/hr of Onapgo. The maximum continuous dosage is 6 mg/hour administered over the waking day (eg, 16 hours).

- Supernus Pharmaceuticals plans to launch Onapgo in the second quarter of 2025. Onapgo will be available as a 98 mg/20 mL (4.9 mg/mL) single-dose cartridge.