Vyalev™ (foscarbidopa/foslevodopa) – New drug approval

- On October 17, 2024, AbbVie announced the FDA approval of Vyalev (foscarbidopa/foslevodopa), for the treatment of motor fluctuations in adults with advanced Parkinson's disease (PD).

- Vyalev is the first subcutaneous (SC) 24-hour infusion of levodopa-based therapy. It is administered via the Vyafuser pump, which is sold separately.

- The efficacy of Vyalev was established in a randomized, double-blind, active-controlled study in 141 patients with advanced PD. Patients enrolled were responsive to levodopa treatment, had motor fluctuations inadequately controlled by their current medications, and experienced a minimum of 2.5 hours of "Off" time per day as assessed by PD diaries. Patients were randomized to either 24-hour/day continuous SC administration of Vyalev plus oral placebo capsules or 24-hour/day continuous SC administration of placebo solution plus oral encapsulated carbidopa-levodopa immediate-release tablets. The primary outcome measure was the mean change from baseline to week 12 in the total daily mean "On" time without troublesome dyskinesia (defined as "On" time without dyskinesia plus "On" time with non-troublesome dyskinesia) based on PD diary.

    — The least squares mean change from baseline in "On" time without troublesome dyskinesia was 2.72 hours with Vyalev vs. 0.97 hour with oral carbidopa-levodopa (difference 1.75, p = 0.0083).

- Vyalev is contraindicated in patients who are currently taking a non-selective monoamine oxidase (MAO) inhibitor or have recently (within 2 weeks) taken a nonselective MAO inhibitor.

- Warnings and precautions for Vyalev include falling asleep during activities of daily living and somnolence; hallucinations/psychosis; impulse control/compulsive behaviors; infusion site reactions and infections; withdrawal-emergent hyperpyrexia and confusion; dyskinesia; cardiovascular ischemic events; and glaucoma.

- The most common adverse reactions (≥ 10% and greater than oral carbidopa-levodopa incidence) with Vyalev use were infusion/catheter site reactions, infusion/catheter site infections, hallucinations, and dyskinesia.

- The recommended continuous infusion rate of Vyalev is based on the total levodopa dosage. The maximum recommended daily dosage is 3,525 mg of the foslevodopa component (equivalent to approximately 2,500 mg levodopa). Refer to the drug label for complete dosing and administration recommendations.

    — Patients should be trained on the proper use of Vyalev and the delivery system prior to initiating treatment and, as necessary, thereafter.

- AbbVie launch plans for Vyalev are pending. Vyalev will be available as a single-dose vial containing 120 mg foscarbidopa and 2,400 mg foslevodopa per 10 mL