Inbrija™ (levodopa) – New drug approval

- On December 21, 2018, Acorda Therapeutics announced the FDA approval of Inbrija (levodopa) inhalation powder, for the intermittent treatment of OFF episodes in people with Parkinson's disease treated with carbidopa/levodopa.

- Parkinson's is a progressive neurodegenerative disorder that causes a range of symptoms including impaired movement, muscle stiffness and tremors. As Parkinson's progresses, people are likely to experience OFF periods, which are characterized by the return of Parkinson's symptoms, which can occur despite underlying baseline therapy.

    — Parkinson's disease affects approximately 1 million people in the U.S. About 40% of people with Parkinson's experience OFF periods.

- Inbrija is the first inhaled formulation of levodopa. Inbrija utilizes Acorda's ARCUS® platform for inhaled therapeutics.

    — The ARCUS technology platform allows systemic delivery of medication through inhalation, by transforming molecules into a light, porous dry powder.

- The efficacy and safety of Inbrija were studied in a placebo-controlled 12-week study enrolling 226 patients with Parkinson's disease experiencing OFF episodes while taking carbidopa/levodopa. The primary endpoint was the change in Unified Parkinson's Disease Rating Scale (UPDRS) Part III motor score from pre-dose OFF state to 30 minutes post-dose, measured at week 12.

    — At week 12, the reduction in UPDRS Part III motor score for Inbrija vs. placebo at 30 minutes post-dose, were -9.8 and -5.9, respectively (Difference from placebo: -3.92; 95% CI: -6.84, -1.00; p = 0.009).

- In addition, the effect of Inbrija on pulmonary function was studied in an open-label, 12-month study enrolling 398 patients with Parkinson's disease taking carbidopa/levodopa. Patients were randomized to receive Inbrija or maintained on their regular oral medication.

    — After 12 months, the average reduction in the forced expiratory volume in 1 second from baseline was the same in both groups (-0.1 L).

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

- Warnings and precautions of Inbrija include falling asleep during activities of daily living and somnolence, withdrawal-emergent hyperpyrexia and confusion, hallucinations/psychosis, impulse control/compulsive behaviors, dyskinesia, bronchospasm in patients with lung disease, glaucoma, and laboratory test abnormalities.

- The most common adverse reactions (≥ 5% and > placebo) of Inbrija use were cough, nausea, upper respiratory tract infection, and sputum discolored.

- The recommended dose of Inbrija is oral inhalation of the contents of two 42 mg capsules (84 mg) as needed, up to 5 times a day.

    — Inbrija capsules are for oral inhalation only and should be used only with the Inbrija inhaler.
    — The maximum dose per OFF period is 84 mg, and the maximum daily dosage is 420 mg.

Continued . . .

    - Inbrija has been shown to be effective only in combination with carbidopa/levodopa.

- Acorda Therapeutics plans to launch Inbrija in the first quarter of 2019. Inbrija will be available as a 42 mg dry powder formulation of levodopa in a white capsule.