

March 29, 2018

TO: The State of Vermont

FR: Acorda Therapeutics, Inc. (Acorda)

RE: INBRIJA™ (levodopa inhalation powder)

- 1. A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally.
 - o INBRIJA[™] is currently only approved in the United States and is under review of the CHMP in Europe. INBRIJA is a unique drug-device combination, consisting of a proprietary inhaled formulation of levodopa delivered by a breath-actuated inhaler. INBRIJA is the first and only inhaled levodopa formulation to treat symptoms of OFF periods as needed in patients taking a carbidopa/levodopa regimen.
 - Acorda markets INBRIJA in the U.S. through our own specialty sales force. The marketing plan includes multiple comprehensive education and training initiatives, provided by our specialty sales force and account directors, for all stakeholders including health care practitioner (HCP) offices, patients, caregivers and Specialty Pharmacies. This includes training materials such as demonstration kits for HCP offices and specialty pharmacies and start kits for patients. People with Parkinson's can suffer from cognitive challenges which make it very difficult for them to navigate the complex health insurance environment. Acorda has an active patient hub in place (Prescription Support Services) to assist patients in that health insurance navigation process to support access to INBRIJA. Our internal team of Regional Reimbursement Directors work directly with HCP offices on specific patient cases to help gain access through their insurance. Acorda offers a free sampling program to help patients and physicians evaluate effectiveness and tolerability, and a free drug Patient Assistance Program for uninsured patients with demonstrated financial hardship who satisfy eligibility criteria. Acorda provides co-pay assistance for commercially insured patients. INBRIJA is a specialty drug distributed through a closed network of specialty pharmacies under contract with Acorda.
 - o When considering the price of INBRIJA one must consider that INBRIJA required over 20 years to develop, from the time the inhaled ARCUS technology was invented at MIT at the lab of Bob Langer. The ARCUS technology transforms molecules in a

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light, dry powder allowing delivery of an effective therapeutic dose of INBRIJA through the lungs. INBRIJA is a major innovation; it is one of only three pulmonary-delivered treatments approved for a non-pulmonary indication. The innovation of ARCUS – the dry powder inhalation system – allows for pulmonary delivery that bypasses the challenges that can be associated with oral levodopa that can lead to variability in absorption, contributing to OFF periods.

- 2. What is the estimated volume of patients that may be prescribed the drug?
 - o In the U.S. there are approximately 1 million people with Parkinson's. Approximately 700,000 are treated with a carbidopa/levodopa regimen with an estimated 350,000 suffering from OFF Periods for which INBRIJA is indicated.
- 3. Was the drug granted breakthrough therapy designation or priority review by the FDA prior to final approval?
 - o No
- 4. What is the date and price of acquisition <u>if</u> the drug was not developed by the manufacturer?
 - Acorda Therapeutics, Inc. ("Acorda") acquired Civitas Therapeutics, Inc. ("Civitas"), which had been developing CVT-301 (now known as INBRIJA), on October 22, 2014, for an aggregate purchase price of \$525 million plus combined acquisition costs of approximately \$12 million. Civitas is now a wholly-owned subisidiary of Acorda. Prior to its acquisition by Acorda, Civitas had been developing INBRIJA from 2010 to 2014, before which the product was being developed by Alkermes. The ARCUS technology upon which INBRIJA is based had previously been developed in the MIT laboratory of Bob Langer.
 - Of the \$525 million aggregate purchase price paid by Acorda to acquire Civitas, \$423 million was allocated to INBRIJA based on the estimated fair value of INBRIJA at the date of acquisition. The balance of the aggregate purchase price was allocated to acquired property and equipment and other tangible current and non-current assets. The amount of the aggregate purchase price paid in excess of the estimated fair value of the assets acquired and liabilities assumed was allocated to goodwill. Because INBRIJA required further clinical testing and development before it could be the subject of a New Drug Application to the FDA, Acorda funded additional investment above the cost that was required to acquire Civitas.

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