Acorda Announces FDA Acceptance of New Drug Application for INBRIJA™ (levodopa inhalation powder)

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ARDSLEY, N.Y.--(BUSINESS WIRE)-- Acorda Therapeutics, Inc. (Nasdaq:ACOR) today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing its New Drug Application (NDA) for INBRIJA. INBRIJA is an investigational inhaled levodopa treatment for symptoms of OFF periods in people with Parkinson’s disease taking a carbidopa/levodopa regimen. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target date of October 5, 2018.

“OFF periods greatly disrupt the lives of people living with Parkinson’s, and there is a significant need for new treatments in this community,” said Burkhard Blank, M.D., Chief Medical Officer of Acorda. “We are excited about the potential to bring this highly innovative treatment option to people living with Parkinson’s, and look forward to working with the FDA throughout the review process.”

The NDA for INBRIJA includes data from a Phase 3 safety and efficacy study (SPAN-PD), as well as results from two long-term safety studies in people with Parkinson's disease. Findings from these studies support the filing of INBRIJA for use on an as-needed basis to address symptoms of OFF periods in patients on a carbidopa/levodopa regimen. Data from the SPAN-PD trial were presented at the International Congress of Parkinson’s Disease and Movement Disorders (MDS) in June 2017.

“People with Parkinson's and physicians need more options to manage this disease,” said Todd Sherer, Ph.D., CEO of The Michael J. Fox Foundation. “Inhaled delivery of levodopa could help the many people living with Parkinson’s facing the complication of OFF periods as their disease progresses.”

The INBRIJA Phase I and II clinical studies were funded in part by grants from The Michael J. Fox Foundation for Parkinson’s Research.
About Parkinson’s and OFF periods

Approximately one million people in the U.S. and 1.2 million Europeans are diagnosed with Parkinson's; OFF periods are experienced by approximately 350,000 in the U.S. and 420,000 in Europe. Parkinson's is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons responsible for producing dopamine. It causes a range of symptoms including impaired movement, muscle stiffness and tremors. As Parkinson's progresses, people will experience OFF periods, which are characterized by the re-emergence of Parkinson's symptoms. This re-emergence can occur even when an individual's treatment regimen has been optimized.

About INBRIJA™ (CVT-301, levodopa inhalation powder) and ARCUS®

INBRIJA is a self-administered, orally inhaled levodopa (L-dopa) therapy in development for the treatment of symptoms of OFF periods in people with Parkinson’s disease taking a carbidopa / levodopa regimen. INBRIJA utilizes Acorda's investigational ARCUS® platform for inhaled therapeutics. INBRIJA was designed to deliver a precise dose of a dry powder formulation of L-dopa to the lung. Oral medication can be associated with variable onset of action, as the medicine is absorbed through the gastrointestinal (digestive) tract before reaching the brain. Inhaled treatments enter the body through the lungs and reach the brain, bypassing the digestive system.

The proprietary name INBRIJA has been conditionally accepted by the U.S. Food and Drug Administration (FDA).

About Acorda Therapeutics

Founded in 1995, Acorda Therapeutics is a biopharmaceutical company focused on developing therapies that restore function and improve the lives of people with neurological disorders. Acorda has a pipeline of novel neurological therapies addressing a range of disorders, including Parkinson's disease and multiple sclerosis. Acorda markets two FDA-approved therapies, including AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg.

Forward-Looking Statement

This press release includes forward-looking statements. All statements, other than statements of historical facts, regarding management's expectations, beliefs, goals, plans or prospects should be considered forward-looking. These statements are subject to risks and uncertainties that could cause actual results to differ materially, including: the ability to realize the benefits anticipated from acquisitions, among other reasons because acquired development programs are generally subject to all the risks inherent in the drug development process and our knowledge of the risks specifically relevant to acquired programs generally improves over time; we may need to raise additional funds to finance our operations and may not be able to do so on acceptable terms; our ability to successfully market and sell Ampyra (dalfampridine) Extended Release Tablets, 10 mg in the U.S., which will likely be
materially adversely affected by the March 2017 court decision in our litigation against filers of Abbreviated New Drug Applications to market generic versions of Ampyra in the U.S.; the risk of unfavorable results from future studies of Inbrija (levodopa inhalation powder) or from our other research and development programs, or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market Inbrija or any other products under development; third party payers (including governmental agencies) may not reimburse for the use of Ampyra, Inbrija or our other products at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; the occurrence of adverse safety events with our products; the outcome (by judgment or settlement) and costs of legal, administrative or regulatory proceedings, investigations or inspections, including, without limitation, collective, representative or class action litigation; competition; failure to protect our intellectual property, to defend against the intellectual property claims of others or to obtain third party intellectual property licenses needed for the commercialization of our products; and failure to comply with regulatory requirements could result in adverse action by regulatory agencies.

These and other risks are described in greater detail in our filings with the Securities and Exchange Commission. We may not actually achieve the goals or plans described in our forward-looking statements, and investors should not place undue reliance on these statements. Forward-looking statements made in this press release are made only as of the date hereof, and we disclaim any intent or obligation to update any forward-looking statements as a result of developments occurring after the date of this press release.


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