Acorda to Present New INBRIJA™ (Levodopa Inhalation Powder) Phase 3 Data at Upcoming MDS Congress

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- Company to host investor webcast to review data from INBRIJA (CVT-301) clinical program on Monday, June 5 at 4:30 pm Eastern / 1:30 pm Pacific

ARDSLEY, N.Y.--(BUSINESS WIRE)--Acorda Therapeutics, Inc. (Nasdaq: ACOR) will present new data from the Phase 3 clinical trial of INBRIJA™ (levodopa inhalation powder) at the International Congress of Parkinson’s Disease and Movement Disorders (MDS), being held in Vancouver, British Columbia from June 4-8, 2017. Acorda is developing INBRIJA (CVT-301) as a treatment for symptoms of OFF periods in people with Parkinson’s disease taking a carbidopa / levodopa regimen. OFF periods refer to the re-emergence of Parkinson’s symptoms.

Data from the INBRIJA Phase 3 safety and efficacy trial, called SPAN-PD, will be featured as a late-breaking poster:

- Inhaled levodopa (CVT-301, 84-mg dose) significantly improves motor function during OFF periods in Parkinson’s disease subjects: A Phase 3 Study (SPAN-PD). Data includes primary and secondary endpoints (ABSTRACT #LBA34).

The Company previously announced positive topline data from the SPAN-PD trial and data from two separate long-term safety studies of INBRIJA.

“We are excited to be preparing an NDA in the U.S. and an MAA in the EU, which we plan to submit by the end of the second quarter and end of the year, respectively. We will present additional findings from the Phase 3 INBRIJA study at the MDS Congress, including key secondary measures,” said Burkhard Blank, M.D., Acorda’s Chief Medical Officer. “Data from our clinical program have shown that INBRIJA has the potential to be an important new treatment option for people with Parkinson’s who experience OFF periods, which can be extremely disruptive in their lives.”
Acorda plans to file a New Drug Application (NDA) for INBRIJA with the U.S. Food and Drug Administration (FDA) by the end of the second quarter of 2017, and a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) by the end of the year.

The Company will host a webcast for investors to provide an overview of the INBRIJA clinical program on June 5, 2017. This will include data being presented at the MDS Congress, as well as additional findings from two long-term safety studies and two special population studies.

Webcast Information

The Company will host an investor webcast to review INBRIJA data on Monday, June 5 at 4:30 pm Eastern / 1:30 pm Pacific. Presentations by Matthew Stern, M.D., University of Pennsylvania, and Peter LeWitt, M.D., Wayne State University School of Medicine, will be followed by a Q&A with Dr. Stern, Dr. LeWitt, Dr. Donald Grosset, M.D., Queen Elizabeth University Hospital (Scotland), Dr. Burkhard Blank, Rick Batycky, Ph.D., Acorda's Chief Technology Officer and Site Head, and Ron Cohen, M.D., Acorda's President and CEO.

The webcast will be available on the Investors Events section of www.acorda.com. Please log in approximately 5 minutes before the scheduled time of the presentation to ensure a timely connection. To participate via conference call, please dial 800-806-5484 (U.S.) or 416-340-2217 (international) and reference the access code 8170198#.

About Parkinson's Disease and OFF Periods

Approximately one million people in the U.S. and 1.2 million Europeans are diagnosed with Parkinson’s disease (PD); 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 PD progresses, people with Parkinson’s experience OFF periods, which are characterized by the re-emergence of PD symptoms. This re-emergence can occur even when an individual’s treatment regimen has been optimized.

OFF periods can be very disruptive to the lives of people with Parkinson’s, their families and caregivers. OFF periods can increase in frequency and severity during the course of the disease.

About INBRIJATM (levodopa inhalation powder) and ARCUS®

INBRIJA (CVT-301) is a self-administered, 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. The proprietary name INBRIJA has been conditionally accepted by the U.S. Food and Drug Administration (FDA).
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.

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, migraine and multiple sclerosis. Acorda markets three FDA-approved therapies, including AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg. For more information, please visit the Company's website at: www.acorda.com.

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 the Biotie and Civitas transactions, 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; the ability to successfully integrate Biotie's operations and Civitas' operations, respectively, into our operations; we may need to raise additional funds to finance our expanded 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 recently announced court decision in our litigation against filers of Abbreviated New Drug Applications (each, an “ANDA”) to market generic versions of Ampyra in the U.S.; third party payers (including governmental agencies) may not reimburse for the use of Ampyra or our other products at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; the risk of unfavorable results from future studies of Ampyra or from our other research and development programs, including INBRIJA (CVT-301, levodopa inhalation powder), 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, any other products under development, or the products that we acquired with the Biotie transaction; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain and maintain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaborator Biogen in connection therewith; 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.


Source: Acorda Therapeutics, Inc.

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