

NEWS RELEASE

# Acorda Announces FDA Extends INBRIJA NDA Review Period

9/13/2018

## New PDUFA Date of January 5, 2019

ARDSLEY, N.Y.--(BUSINESS WIRE)-- Acorda Therapeutics, Inc. (Nasdaq:ACOR) today announced that the U.S. Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) goal date for its review of the New Drug Application (NDA) of INBRIJA™ (levodopa inhalation powder) from October 5, 2018 to January 5, 2019.

This extension is related to recent submissions Acorda made in response to requests from FDA for additional information on chemistry, manufacturing and controls (CMC). FDA determined that these submissions constitute a major amendment and will take additional time to review.

"We look forward to continuing our constructive dialogue with FDA," said Ron Cohen, M.D., Acorda's President and CEO. "We remain committed to bringing INBRIJA to approval for people with Parkinson's who experience OFF periods, which are highly disruptive and in need of new therapeutic options."

The FDA accepted Acorda's NDA for INBRIJA in February 2018.

## About Parkinson's and OFF periods

Parkinson's is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons responsible for producing dopamine. Approximately one million people in the U.S. and 1.2 million Europeans are diagnosed with Parkinson's; it is estimated that approximately 40 percent of people with Parkinson's experience OFF periods. 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 motor and non-motor symptoms. This re-emergence can occur even when an individual's treatment regimen has been optimized.

## About INBRIJA™ (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 through 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 trial court decision in our litigation against filers of Abbreviated New Drug Applications to market generic versions of Ampyra in the U.S., which was affirmed by the appellate court in September 2018; 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; risks associated with complex, regulated manufacturing processes for

pharmaceuticals, which could affect whether we have sufficient commercial supply of Inbrija to meet market demand, if it receives regulatory approval; 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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