NEWS RELEASE

# Acorda Receives Refusal to File Letter from FDA for INBRIJA™ (CVT-301, levodopa inhalation powder) New Drug Application

8/29/2017

ARDSLEY, N.Y.--(BUSINESS WIRE)-- Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that it received a Refusal to File (RTF) letter from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for INBRIJA. INBRIJA is an investigational treatment for symptoms of OFF periods in people with Parkinson's disease taking a carbidopa/levodopa regimen.

Upon its preliminary review, FDA determined that the NDA, submitted on June 26, 2017, was not sufficiently complete to permit a substantive review. FDA specified two reasons for the RTF: first, the date when the manufacturing site would be ready for inspection, and, second, a question regarding the submission of the drug master production record. FDA also requested additional information at resubmission, which was not part of the basis for the RTF.

The Company will seek immediate guidance, including a Type A meeting with the FDA, to respond to the issues, which it believes are addressable, and to seek clarification of what additional information will be required. The FDA has not requested or recommended additional clinical efficacy or safety studies.

"We will work with the FDA as quickly as possible to address the open issues and to clarify the path to successfully re-file our application," said Ron Cohen, M.D., Acorda's President and CEO. "We remain confident in INBRIJA's data package and its promise as an important new therapy for people with Parkinson's disease. We see tremendous long-term value in its solid clinical profile, significant commercial opportunity and strong IP, and we remain focused on working to bring patients this important new therapy."

## 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 three 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 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 into our operations; 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 recently announced 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 (CVT-301, levodopa inhalation powder), tozadenant 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, tozadenant, 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; failure to 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.

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