

Acorda to Discontinue Development of Dalfampridine for Treatment of Post-Stroke Walking Difficulties

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ARDSLEY, N.Y.--(BUSINESS WIRE)-- Acorda Therapeutics, Inc. (Nasdaq:**ACOR**) today announced that the MILESTONE clinical study did not show sufficient efficacy to support further development of dalfampridine to improve post-stroke walking difficulties (PSWD).

“We are disappointed by this outcome. The study indicated there was activity related to walking in people with PSWD, as suggested by the prior Phase 2 study, but overall this was not sufficiently clinically meaningful. I want to express our gratitude to the study participants, their care partners and clinicians, who gave their time and commitment to this research,” said Ron Cohen, M.D., President and CEO of Acorda. “This outcome underscores the risks that companies in the biopharmaceutical industry must take in order to develop innovative medicines. Over the past three years, we have successfully diversified our pipeline portfolio to account for this risk. We plan to focus R&D resources on developing our promising late-stage Parkinson’s disease therapies, CVT-301 and tozadenant, as well as advancing our earlier stage assets, CVT-427 in migraine, SYN120 in Parkinson’s disease dementia, and rHlgM22 in MS.”

As part of the PSWD development program, a multi-dose pharmacokinetic (PK) study confirmed the Company has developed a potentially viable once-daily (QD) formulation of dalfampridine.

MILESTONE Efficacy and Safety Findings

The Company elected to stop enrollment and to conduct an unblinded analysis of the MILESTONE trial after reaching enrollment of 377 participants. This analysis included 368 participants who received either 10 mg or 7.5 mg of dalfampridine twice daily (BID) or placebo. The primary outcome measure of the study was the proportion of participants who showed at least a 20% improvement on the Two Minute Walk Test (2MinWT) at Week 12 as compared to baseline. The 2MinWT measures the distance a subject can walk in 2 minutes, and is a validated scale

used to assess walking capacity.

The study found that 23 of 121 (19.0%) participants receiving 10 mg of dalfampridine BID and 17 of 121 (14.0%) participants receiving 7.5 mg of dalfampridine BID showed at least a 20% improvement on the 2MinWT, compared to 17 of 126 (13.5%) participants receiving placebo.

In this study, dalfampridine was well tolerated in the post-stroke population. The safety profile overall was similar to that observed in multiple sclerosis clinical trials and post-marketing surveillance. The most common adverse events ($\geq 5\%$) reported in this study were: falls (10 mg: 10.7%, 7.5 mg: 9.5%, placebo: 5.6%), urinary tract infections (10 mg: 9.0%, 7.5 mg: 6.3%, placebo: 2.4%), dizziness (10 mg: 3.3%, 7.5 mg: 7.9%, placebo: 2.4%) and fatigue (10mg: 2.5%, 7.5 mg: 3.2%, placebo: 6.3%). There were no seizures reported in the dalfampridine 10 mg group. There were 2 seizures reported in the 7.5 mg group and 3 reported in the placebo group.

Additional data from the MILESTONE study will be presented at a future medical meeting.

About Acorda Therapeutics

Founded in 1995, Acorda Therapeutics is a biotechnology company focused on developing therapies that restore function and improve the lives of people with neurological disorders.

Acorda has an industry leading 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.; 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 CVT-301 or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market CVT-301, 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.

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