Acorda Therapeutics Announces Positive AMPYRA® (dalfampridine) Phase 2 Data in People with Post-Stroke Deficits

- Company Plans to Continue Clinical Development in Post-Stroke Deficits
- Safety Findings Consistent with Previous Clinical Trials and Post-Marketing Experience in Multiple Sclerosis
- Separate Proof-of-Concept Study in Cerebral Palsy Confirms Safety; Efficacy Measures Require Further Analysis
- Webcast at 8:30 am Today to Review Study Findings

Press Release: Acorda Therapeutics, Inc. – 2 hours 58 minutes ago

ARDSLEY, N.Y.--(BUSINESS WIRE)--

Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that a proof-of-concept trial found dalfampridine extended release (ER) tablets, marketed as AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg, improved walking in people with post-stroke deficits. Post-stroke deficits refer to chronic neurological deficits, such as impaired walking, motor and sensory function and manual dexterity that persist in people who have had a stroke.

“There were clear efficacy signals in the dalfampridine-ER post-stroke deficits trial and we therefore plan to proceed with a clinical development program for this indication. A top-line analysis of the data found dalfampridine-ER improved walking for people with mobility impairment resulting from ischemic stroke. Dalfampridine-ER treatment was also associated with a positive change versus placebo on a scale of functional independence in this study,” said Ron Cohen, M.D., Acorda’s President and Chief Executive Officer. “We are analyzing the data further to better understand the entirety of the results. After we complete the analysis, we plan to discuss the development program with the FDA. There are more than seven million stroke survivors in the United States, and approximately half of them have some lasting mobility impairment. There are no medications currently available for these patients, so new therapies are desperately needed.”

This study included 83 participants who had experienced an ischemic stroke at least six months prior to enrollment and had chronic motor deficits. As part of the crossover design, participants received both dalfampridine-ER 10 mg and placebo for 14 days twice daily, with a wash-out period in between during which participants received placebo. The primary goals of the study were to assess safety and tolerability, as well as to explore various efficacy measures.

Key Safety Findings from Post-Stroke Deficits Trial

The safety findings in this study were consistent with previous clinical trials and post-marketing experience of AMPYRA in multiple sclerosis (MS).

The most common adverse events reported in the study were dizziness (10.4% dalfampridine-ER, 2.5% placebo), nausea (3.9% dalfampridine-ER, 6.2% placebo), fatigue (5.2% dalfampridine-ER, 3.7% placebo), insomnia (5.2% dalfampridine-ER, 2.5% placebo) and arthralgia (2.6% dalfampridine-ER, 3.7% placebo).

Three participants experienced a seizure during the study. One occurred while the participant was taking placebo (without prior exposure to dalfampridine-ER), one occurred while the participant was taking dalfampridine-ER, and one occurred due to an intentional overdose of dalfampridine-ER. The overdose was judged by the study investigator to be a

suicide attempt related to a recent family tragedy. All three participants recovered fully.

Key Efficacy Findings from Post-Stroke Deficits Trial

Improvement in walking was measured by the Timed 25-Foot Walk (T25FW). Using the full crossover design, walking speed increased while participants were taking dalfampridine-ER compared to placebo (p

Participants also showed a positive change on the Functional Independence Measurement (FIM) scale while taking dalfampridine-ER compared to placebo. The FIM scale assesses an individual's ability to perform daily tasks such as bathing, grooming, eating, and walking independently.

Other exploratory efficacy measures in the study are currently being analyzed.

Cerebral Palsy Study Update

A separate proof-of-concept trial including 24 participants explored the use of dalfampridine-ER 10 mg dosed twice daily in adults with cerebral palsy (CP).

The safety findings in this study were consistent with previous clinical trials and post-marketing experience of AMPYRA in MS. The most commonly reported adverse events were headache (12.5% dalfampridine-ER, 4.2% placebo), fatigue (12.5% dalfampridine-ER, 0% placebo), insomnia (8.3% dalfampridine-ER, 4.2% placebo), diarrhea (4.2% dalfampridine-ER, 4.2% placebo) and nausea (4.2% dalfampridine-ER, 4.2% placebo). There were no serious adverse events reported.

Efficacy data from this study suggested potential treatment activity on measures of walking and hand strength; however, these data are still being analyzed to determine if they are sufficiently robust to warrant further clinical studies.

The Company plans to present data from the post-stroke deficits and CP trials in appropriate medical forums following additional analysis of the data.

AMPYRA is approved by the U.S. Food and Drug Administration (FDA) for the improvement of walking in people with MS. This was demonstrated by an increase in walking speed. The findings in post-stroke deficits and CP do not impact AMPYRA's proven safety and efficacy profile in people with MS.

Webcast and Conference Call

Ron Cohen, M.D., President and Chief Executive Officer, and Andrew Blight, Ph.D., Chief Scientific Officer, will host a conference call today at 8:30 a.m. ET to review the study findings.

To participate in the conference call, please dial 800-510-0219 (domestic) or 617-614-3451 (international) and reference the access code 93715573. The presentation will be available via a live webcast on the Investor section of www.acorda.com.

A replay of the call will be available from 10:30 a.m. ET on April 15, 2013 until midnight on May 15, 2013. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 18022123. The archived webcast will be available for 30 days in the Investor Relations section of the Acorda website at www.acorda.com.

Important Safety Information

Do not take AMPYRA if you have ever had a seizure or have certain types of kidney problems.

Take AMPYRA exactly as prescribed by your doctor.

You could have a seizure even if you never had a seizure before. Your chance of having a seizure is higher if you take too much AMPYRA or if your kidneys have a mild decrease of function, which is common after age 50.

Your doctor may do a blood test to check how well your kidneys are working, if that is not known before you start taking

AMPYRA.

AMPYRA may cause serious allergic reactions, including rare occurrence of anaphylaxis.

AMPYRA should not be taken with other forms of 4-aminopyridine (4-AP, fampridine), since the active ingredient is the same.

The most common adverse events for AMPYRA in MS patients were urinary tract infection, trouble sleeping, dizziness, headache, nausea, weakness, back pain, and problems with balance.

Before taking AMPYRA tell your doctor if you are pregnant or plan to become pregnant. It is not known if AMPYRA will harm your unborn baby.

Tell your doctor if you are breast-feeding or plan to breast-feed. It is not known if AMPYRA passes into your breast milk. You and your doctor should decide if you will take AMPYRA or breast-feed. You should not do both.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

About AMPYRA (dalfampridine)

AMPYRA is a potassium channel blocker approved as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed. AMPYRA, which was previously referred to as Fampridine-SR, is an extended release tablet formulation of dalfampridine (4-aminopyridine, 4-AP), and is known as prolonged-, modified, or sustained-release fampridine (FAMPYRA®) in some countries outside the United States (U.S.).

In laboratory studies, dalfampridine extended release tablets has been found to improve impulse conduction in nerve fibers in which the insulating layer, called myelin, has been damaged.

AMPYRA is being developed and commercialized in the U.S. by Acorda Therapeutics; FAMPYRA is being developed and commercialized by Biogen Idec in markets outside the U.S. based on a licensing agreement with Acorda. AMPYRA and FAMPYRA are manufactured globally by Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc, based on a supply agreement with Acorda.

AMPYRA is available by prescription in the United States. For more information about AMPYRA, including patient assistance and co-pay programs, healthcare professionals and people with MS can contact AMPYRA Patient Support Services at 888-881-1918. AMPYRA Patient Support Services is available Monday through Friday, from 8:00 a.m. to 8:00 p.m. Eastern Time. For full U.S. Prescribing Information and Medication Guide, please visit: www.AMPYRA.com.

About Acorda Therapeutics

Acorda Therapeutics is a biotechnology company focused on developing therapies that restore function and improve the lives of people with MS, spinal cord injury and other neurological conditions.

Acorda markets AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg, in the United States as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an improvement in walking speed. AMPYRA is marketed outside the United States as FAMPYRA® (prolonged-release fampridine tablets) by Biogen Idec under a licensing agreement from Acorda. AMPYRA and FAMPYRA are manufactured under license from Alkermes Pharma Ireland Limited.

The Company also markets ZANAFLEX CAPSULES® (tizanidine hydrochloride) and Zanaflex tablets, a short-acting drug for the management of spasticity. Acorda also receives sales royalties on tizanidine hydrochloride capsules, an authorized generic version of ZANAFLEX CAPSULES, distributed by Actavis, Inc. under its agreement with Acorda.

Acorda has one of the leading pipelines in the industry of novel neurological therapies. The Company is developing Diazepam Nasal Spray for treatment of certain epileptic seizures. It is also studying AMPYRA to improve a range of

functional impairments caused by MS, as well as its potential for use in other neurological conditions, including cerebral palsy and post-stroke deficits. In addition, Acorda is developing clinical stage compounds AC105 for acute treatment of spinal cord injury, GGF2 for treatment of heart failure and rHIgM22, a remyelinating monoclonal antibody, for the treatment of MS. GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and spinal cord injury. Chondroitinase, an enzyme that encourages nerve plasticity in spinal cord injury, is in preclinical development.

Acorda Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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 our ability to successfully market and sell 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 Diazepam Nasal Spray or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market Diazepam Nasal Spray or other products under development; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaboration partner Biogen Idec in connection therewith; competition, including the impact of generic competition on Zanaflex Capsules revenues; 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; failure to comply with regulatory requirements could result in adverse action by regulatory agencies; and the ability to obtain additional financing to support our operations. These and other risks are described in greater detail in Acorda Therapeutics' filings with the Securities & Exchange Commission. Acorda may not actually achieve the goals or plans described in its forward-looking statements, and investors should not place undue reliance on these statements. Forward-looking statements made in this release are made only as of the date hereof, and Acorda disclaims any intent or obligation to update any forward-looking statements as a result of developments occurring after the date of this release.

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