Acorda Therapeutics Presents Preclinical Data Showing Dalfampridine Improves Motor Function in Chronic Stroke

First ever data to demonstrate improvement in motor function following stroke with oral drug treatment initiated several weeks after event

HAWTHORNE, N.Y., Feb 03, 2012 (BUSINESS WIRE) -- Acorda Therapeutics, Inc. /quotes/zigman/91130/quotes/nls/acor ACOR -4.42% presented data showing that treatment with dalfampridine improved motor function in a preclinical model of stroke, with treatment initiated at least four weeks following the ischemic event. These data were presented on February 2 at the American Heart Association/American Stroke Association International Stroke Conference in New Orleans, LA. Dalfampridine, also known as 4-aminopyridine, is the active chemical ingredient in AMPYRA(R) (dalfampridine) Extended Release Tablets, 10 mg.

"These are the first preclinical data to show an oral pharmacologic treatment can improve function in chronic, or long term, stroke. We are excited by these results and plan to begin proof-of-concept human clinical trials of AMPYRA in people with chronic stroke later this year," said Andrew R. Blight, Ph.D., Acorda Therapeutics' Chief Scientific Officer. "The majority of the nearly seven million people in the United States who live with the long term effects of a stroke have motor function deficits, such as walking impairment, but there are no established treatments other than physical therapy to address these impairments."

A late-breaking science presentation, entitled "Dalfampridine Improves Sensorimotor Function in Rats with Chronic Deficits Following Middle Cerebral Artery Occlusion," presented by Acorda scientist Jennifer Iaci, reviewed data from three study groups that received treatment beginning four weeks after a permanent middle cerebral artery occlusion (pMCAO). The neurological impairments that result are expected to be permanent by four weeks, which represents the chronic stage of stroke. Each group received three treatment phases over the course of the study: high and low doses of dalfampridine, and placebo. The order of the treatment phases was different for each group, with a 10 day washout period between each phase.

Researchers assessed functional improvement using a battery of standard motor function tests in both the forelimbs and hind limbs. In each of the three study groups, treatment with dalfampridine resulted in significant improvement in function compared to placebo across all measures during the respective treatment periods. Improvements in the high dose phase were consistently better than those seen in the low dose phase.

"In addition to the seven million Americans living with the consequences of a prior stroke, there are close to 800,000 people in the United States who have new stroke events each year. The resulting disability has a major impact on the person who suffers the stroke as well as on their caregivers, and places a significant burden on the healthcare system," said Seth Finklestein, M.D., Chairman and Chief Scientific Officer of Biotrofix, a preclinical research organization that conducted research for this study in partnership with Acorda. "These are the first data from a well-controlled preclinical study that have demonstrated improvement in motor function related to walking and upper body

movement. Developing a therapeutic option that can improve function would represent a potential major advance in the standard of care for stroke survivors."

Acorda plans to begin a proof-of-concept trial of AMPYRA in stroke by the end of 2012. This study will evaluate the use of AMPYRA in stroke patients with chronic neurologic deficits, including walking impairment.

AMPYRA is approved 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 known as prolonged-, modified-, or sustained-release fampridine (FAMPYRA(R)) in some countries outside the United States.

Important Safety Information

AMPYRA can cause seizures; the risk of seizures increases with increasing AMPYRA doses. AMPYRA is contraindicated in patients with a prior history of seizure. Discontinue AMPYRA use if seizure occurs.

AMPYRA is contraindicated in patients with moderate or severe renal impairment (CrCl less-than or equal to 50 mL/min); the risk of seizures in patients with mild renal impairment (CrCl 51-80 mL/min) is unknown, but AMPYRA plasma levels in these patients may approach those seen at a dose of 15 mg twice daily, a dose that may be associated with an increased risk of seizures; estimated CrCl should be known before initiating treatment with AMPYRA.

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

Urinary tract infections were reported more frequently as adverse reactions in patients receiving AMPYRA 10 mg twice daily compared to placebo.

The most common adverse events (incidence greater-than or equal to 2% and at a rate greater than the placebo rate) for AMPYRA in MS patients were urinary tract infection, insomnia, dizziness, headache, nausea, asthenia, back pain, balance disorder, multiple sclerosis relapse, paresthesia, nasopharyngitis, constipation, dyspepsia, and pharyngolaryngeal pain.

For full U.S. Prescribing Information and Medication Guide for AMPYRA, 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(R) (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(R) (prolonged-release fampridine tablets)by Biogen

Idec under a licensing agreement from Acorda. AMPYRA and FAMPYRA are sold under a license from Alkermes Pharma Ireland Limited and manufactured by Alkermes Pharma Ireland Limited and other parties.

The Company also markets ZANAFLEX CAPSULES(R) (tizanidine hydrochloride) and Zanaflex tablets, a short-acting drug for the management of spasticity.

Acorda is developing an industry-leading pipeline of novel neurological therapies. The Company is studying AMPYRA to improve a range of functional impairments caused by MS, as well as its use in other neurological conditions, including cerebral palsy and chronic stroke. In addition, Acorda is developing clinical stage compounds AC105 for acute treatment of spinal cord injury and GGF2 for treatment of heart failure. GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and spinal cord injury. Additional preclinical programs include rHIgM22, a remyelinating monoclonal antibody for the treatment of MS, and chondroitinase, an enzyme that encourages nerve plasticity in spinal cord injury.

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 Acorda Therapeutics' ability to successfully market and sell Ampyra in the United States; third party payors (including governmental agencies) may not reimburse for the use of Ampyra 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; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of Ampyra outside of the United States and our dependence on our collaboration partner Biogen Idec in connection therewith; competition, including the impact of anticipated potential generic competition on Zanaflex Capsules revenues; failure to protect Acorda Therapeutics' 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; the ability to obtain additional financing to support Acorda Therapeutics' operations; and, unfavorable results from our research and development programs. These and other risks are described in greater detail in Acorda Therapeutics' filings with the Securities and Exchange Commission. Acorda Therapeutics 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 Therapeutics disclaims 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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