Axsome Therapeutics Announces Enrollment of the First Patient in a Phase 3 Trial of AXS-02 for Complex Regional Pain Syndrome (CRPS)

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AXS-02 is an oral, non-opioid treatment with a novel mechanism of action for chronic pain
CRPS is a debilitating pain syndrome with no approved pharmacological treatment

NEW YORK, Aug. 10, 2015 (GLOBE NEWSWIRE) — Axsome Therapeutics, Inc., a biopharmaceutical company developing novel therapies for the treatment of pain and other central nervous system (CNS) disorders, today announced the enrollment of the first patient in the CREATE-1 (CRPS Treatment Evaluation 1) study—a Phase 3 trial evaluating the efficacy and safety of AXS-02 (disodium zoledronate) for the treatment of pain associated with complex regional pain syndrome (CRPS). AXS-02 is a potent osteoclast inhibitor being developed as an oral, targeted, non-opioid, potentially first-in-class therapeutic for chronic pain.

“CRPS patients live with a level of pain that is unimaginable for most of us. As there are no approved treatments for this serious disease, it represents a high unmet medical need,” said Leonardo Kapural, M.D., Ph.D., Professor of Anesthesiology at Wake Forest University, and Clinical Director of the Chronic Pain Center at Wake Forest University Health Sciences Center. “This is an important clinical trial as it may increase the treatment options for those living with CRPS.”

“The Reflex Sympathetic Dystrophy Syndrome Association (RSDSA) supports research to develop better treatments and a cure for this devastating condition,” said Jim Broatch, Executive Vice President and Director of the RSDSA. “Clinical trials such as the CREATE-1 study is an example of the type of research that could yield new options to improve the lives of individuals with CRPS.”

“We are pleased to enroll the first patient in the CREATE-1 trial,” said Randall Kaye, M.D., Chief Medical Officer of Axsome Therapeutics. “This multi-national study will further our understanding of the potential role of AXS-02 in the treatment of pain associated with CRPS. The launch of this Phase 3 trial comes on the heels of our recent FDA Fast Track designation for AXS-02 in CRPS.”

In March of this year, the United States Food and Drug Administration (FDA) granted Fast Track designation for AXS-02 for the treatment of pain associated with CRPS. This designation provides greater access to and more frequent communication with the FDA throughout the entire drug development and review process, with the goal of possibly expediting approval. Fast Track designation also gives Axsome the opportunity to potentially submit sections of the AXS-02 new drug application (NDA) for CRPS on a rolling basis, and allows AXS-02 to be considered for priority review at the time of submission. AXS-02 has also been granted Orphan Drug Designation by the FDA, and Orphan Medicinal Product Designation by the European Medicine Agency (EMA) for the treatment of CRPS.

“As an organization, we aim to research and bring to market innovative therapies for sufferers of chronic pain and CNS diseases,” said Herriot Tabuteau, M.D., Chief Executive Officer of Axsome Therapeutics. “We are committed to working to find solutions for the CRPS patient community.”

About the CREATE-1 Study

This Phase 3 multi-national, multi-center, randomized, double-blind, placebo-controlled trial is designed to evaluate the efficacy and safety of AXS-02 in the treatment of pain associated with CRPS. The study is expected to enroll 190 patients at sites in the United States, Canada, Europe, and Australia. Eligible patients will be randomized in a 1:1 ratio to be treated with AXS-02 or placebo. The primary efficacy measure is the change in patient reported pain intensity, measured using the 0-10 Numerical Rating Scale (NRS). Secondary outcome measures include assessments of the change in the Brief Pain Inventory (BPI) Pain Score, Patients’ and Clinicians’ Global Impression of Change (PGI-C and CGI-C, respectively), quality of life measures, and bone turnover markers.

More information about the CREATE-1 study is available at www.clinicaltrials.gov.

To learn about eligibility, patients can visit www.CRPStrial.com.

About AXS-02

AXS-02 (disodium zoledronate) is a potent osteoclast inhibitor being developed as an oral, targeted, non-opioid, potentially first-in-class therapeutic for chronic pain, including pain associated with CRPS. AXS-02 has a high affinity for bone mineral, and reduces osteoclast activity by inhibiting the farnesyl pyrophosphate synthase (FPPS) enzyme.

AXS-02 is an investigational medication not approved by the FDA. The safety and efficacy of AXS-02 have not yet been established.

About Complex Regional Pain Syndrome (CRPS)

CRPS, previously known as Reflex Sympathetic Dystrophy (RSD), is a debilitating condition characterized by severe and continuous pain in a limb, accompanied by autonomic, sensory, motor and trophic changes. For many patients the pain and associated loss of function result in significant and sometimes permanent disability. There is currently no drug approved for the treatment of CRPS in the United States or the European Union.

More information about CRPS is available at the National Institute of Neurological Disorders website (www.ninds.nih.gov/disorders/reflex_sympathetic_dystrophy/reflex_sympathetic_dystrophy.htm).

Patient support information is available at the RSDSA website (www.rsds.org).

About Axsome Therapeutics, Inc.

Axsome Therapeutics, Inc. is a biopharmaceutical company developing novel therapies for the management of pain and other CNS disorders. By focusing on this therapeutic area, Axsome is addressing growing markets where current treatment options are limited or inadequate. Axsome has a portfolio of clinical development stage as well as research stage products. Axsome Therapeutics aims to become a fully integrated biopharmaceutical company that develops and commercializes differentiated products, which increase the armamentarium of caregivers and improve the lives of patients. While the focus of the company is on developing its internally derived product candidates, Axsome also evaluates potential in-licensing opportunities to supplement its current portfolio.

Forward Looking Statements

Certain matters discussed in this press release are “forward-looking statements”. We may, in some cases, use terms such as “predicts,” “believes,” “potential,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. In particular, the Company’s statements regarding trends and potential future results are examples of such forward-looking statements. The forward-looking statements include risks and uncertainties, including, but not limited to, the success, timing and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates, including statements regarding the timing of initiation and completion of the trials; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, our product candidates; the Company’s ability to successfully defend its intellectual property or obtain the necessary licenses at a cost acceptable to the Company, if at all; the successful implementation of the Company’s research and development programs and collaborations; the success of the Company’s license agreements; the acceptance by the market of the Company’s product candidates, if approved; and other factors, including general economic conditions and regulatory developments, not within the Company’s control. The factors discussed herein could cause actual results and developments to be materially different from those expressed in or implied by such statements. The forward-looking statements are made only as of the date of this press release and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstance.

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