Axsome Therapeutics, Inc. Logo

Axsome Announces CREATE-1 Interim Analysis Expected Year-End 2017

September 7, 2017

Interim analysis results for both CREATE-1 and COAST-1 trials anticipated late December to early January

NEW YORK, Sept. 07, 2017 (GLOBE NEWSWIRE) -- Axsome Therapeutics, Inc. (NASDAQ:AXSM), a clinical-stage biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders, today announced that the interim efficacy analysis of the Phase 3 CREATE-1 trial of AXS-02 in complex regional pain syndrome (CRPS) is expected year-end 2017. The interim analysis for CREATE-1 will be performed by an independent data monitoring committee (IDMC) and results of the analysis are expected late December 2017 to early January 2018. Approximately 80 subjects were randomized in the trial as of the end of August 2017. Enrollment of subjects in the trial is ongoing and will continue through the interim analysis.

The IDMC will also perform the planned interim analysis of the Phase 3 COAST-1 trial of AXS-02 in knee osteoarthritis (OA) associated with bone marrow lesions (BMLs). Because of member availability, and for efficiency, the IDMC will analyze both CREATE-1 and COAST-1 trials at the same committee meeting. Therefore interim analysis results for COAST-1 are now also expected late December 2017 to early January 2018, versus previous anticipated timing of the third quarter of 2017.

“Our team is excited as we near initial data on AXS-02, our targeted, disease-specific, non-opioid product candidate for chronic pain,” said Herriot Tabuteau, M.D., Chief Executive Officer of Axsome. “The interim analysis for the CREATE-1 trial in CRPS is being conducted for efficacy, while the COAST-1 interim analysis in knee OA associated with BMLs is being conducted to assess the assumptions used to determine the sample size of the study. We look forward to the results of these analyses.”

About Complex Regional Pain Syndrome (CRPS)

CRPS is a debilitating condition characterized by severe, continuous, burning or throbbing pain in a limb. The excessive pain is accompanied by changes in skin color, temperature and/or swelling. It is considered to be one of the most painful conditions, results in loss of physical function, and can lead to significant and sometimes permanent disability. There is currently no medication approved for the treatment of CRPS.

About Knee Osteoarthritis (OA) associated with Bone Marrow Lesions (BMLs)

Knee OA is a disorder characterized by periarticular bone changes, progressive loss of articular cartilage, joint space narrowing, and eventual total joint failure. It is clinically manifested by knee pain, significant physical disability, and reduced quality of life. BMLs are regions of increased signal intensity on magnetic resonance imaging (MRI) of the knee in patients with knee OA. BMLs are strongly associated with the presence and severity of knee pain, and predict disease severity and structural progression in patients with knee OA, based on published studies. Results of epidemiological studies suggest that there are approximately 7 million symptomatic patients in the United States, 50 years of age and older, with radiographic knee OA and BMLs.

About AXS-02

AXS-02 (disodium zoledronate tetrahydrate) is a potent osteoclast inhibitor being developed as an oral, targeted, non-opioid, potentially first-in-class therapeutic for chronic pain. AXS-02 is dosed once per week for 6 weeks and thereafter may have a duration of effect measured in months. AXS-02 has a high affinity for bone mineral, and reduces osteoclast activity by inhibiting the farnesyl pyrophosphate synthase (FPPS) enzyme. AXS-02 is being developed in three separate Phase 3 clinical programs: complex regional pain syndrome (CRPS), knee osteoarthritis (OA) associated with bone marrow lesions (BMLs), and chronic low back pain (CLBP) associated with Modic changes (MCs). Phase 3 trials are underway with AXS-02 in CRPS (the CREATE-1 study) and knee OA associated with BMLs (the COAST-1 study), and a Phase 3 trial is planned in CLBP. AXS-02 is an investigational product candidate not approved by the FDA. The safety and efficacy of AXS-02 have not yet been established.

About Axsome Therapeutics, Inc.

Axsome Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders for which there are limited treatment options. Axsome’s product candidate portfolio includes three clinical-stage candidates, AXS-02, AXS-05, and AXS-06. AXS-05 is currently in a Phase 3 trial in treatment resistant depression (TRD) and a Phase 2/3 trial in agitation in patients with Alzheimer’s disease (AD). AXS-02 is currently in Phase 3 trials in complex regional pain syndrome (CRPS) and knee osteoarthritis (OA) associated with bone marrow lesions (BMLs) with an additional Phase 3 trial planned in chronic low back pain (CLBP) associated with Modic changes (MCs). A Phase 1 trial of AXS-06 has been completed. AXS-02, AXS-05, and AXS-06 are investigational drug products not approved by the FDA. For more information, please visit the company website at www.axsome.com. The company may occasionally disseminate material, nonpublic information on the company website.

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, futility analyses and receipt of interim results; 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.

Axsome Contact:
Mark Jacobson
Vice President, Operations
Axsome Therapeutics, Inc.
25 Broadway, 9th Floor
New York, NY 10004
Tel: 212-332-3243
Email: mjacobson@axsome.com
www.axsome.com

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