Axsome Therapeutics Initiates Phase 3 Study of AXS-05 for Treatment Resistant Depression

March 17, 2016 7:00 AM ET

First Patient Enrolled in the STRIDE-1 Study

Second Product Candidate Axsome Has Advanced into a Pivotal Trial

NEW YORK , March 17, 2016 (GLOBE NEWSWIRE) -- Axsome Therapeutics, Inc. (NASDAQ:AXSM), a clinical-stage biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders, enrolled the first patient in the STRIDE-1 (Symptom Treatment in Resistant Depression 1) study, a Phase 3 trial evaluating the efficacy and safety of AXS-05 for the treatment of treatment resistant depression (TRD). AXS-05 is an innovative oral therapeutic, with activity at several key neurotransmitter systems, being developed for the treatment of CNS disorders. AXS-05 combines mechanisms of action of several distinct antidepressant drug classes.

“Treatment resistant depression is debilitating and life-threatening for patients, while also being distressing for family members. Unfortunately, there are few viable options for patients living with depression if initial treatments do not work,” said Maurizio Fava, M.D., Slater Family Professor of Psychiatry at Harvard Medical School and Executive Vice Chair of the Department of Psychiatry at Massachusetts General Hospital . “Research into potential new medications with novel mechanisms of action is critical to addressing this public health need.”

“We believe that AXS-05 holds promise in this indication due its multiple mechanisms of action, which result in a unique pharmacological profile that may have broad therapeutic applicability,” said Randall Kaye, M.D., Chief Medical Officer of Axsome. “We look forward to learning more about AXS-05 and its potential for treatment resistant depression through the STRIDE-1 study.”

“The launch of STRIDE-1 is a significant milestone for Axsome,” said Herriot Tabuteau, M.D., Chief Executive Officer of Axsome. “Axsome has now advanced two product candidates into pivotal trials. We remain committed to developing novel therapeutics for unmet medical needs.”

About the STRIDE-1 Study

STRIDE-1 (Symptom Treatment in Resistant Depression 1) is a Phase 3, randomized, double-blind, active controlled trial to assess the efficacy and safety of AXS-05 in the treatment of treatment resistant depression (TRD). Patients with major depressive disorder (MDD) who have previously failed one or two antidepressant treatments will be treated in an open-label fashion with bupropion during a 6-week lead-in period. Patients who fail to respond to bupropion during this lead-in period will be randomly assigned in a 1:1 ratio to receive bupropion or AXS-05 in a double-blind fashion for 6 weeks. The primary endpoint is the change in the Montgomery -Åsberg Depression Rating Scale (MADRS) after 6 weeks of treatment.

About AXS-05

AXS-05 is an innovative oral therapeutic, consisting of bupropion and dextromethorphan, which is being developed for the treatment of central nervous system (CNS) disorders. Dextromethorphan is an NMDA receptor antagonist, sigma-1 receptor agonist, and inhibitor of the serotonin and norepinephrine transporters. Bupropion is a norepinephrine and dopamine reuptake inhibitor, and nicotinic acetylcholine receptor antagonist. In addition to its CNS activity, bupropion also serves to increase the bioavailability of dextromethorphan. AXS-05 is an investigational product not approved by the FDA .

About Treatment Resistant Depression (TRD)

Patients diagnosed with major depressive disorder (MDD) are defined as having TRD if they have failed two or more antidepressant therapies. MDD is a serious condition characterized by depressed mood or a loss of interest or pleasure in daily activities consistently for at least a two-week period, and which impairs social, occupational, educational, or other important functioning. According to the National Institute of Health , an estimated 6.7% of U.S. adults experience MDD each year. Nearly two-thirds of diagnosed and treated patients do not experience adequate treatment response with first-line therapy, and the majority of these initial failures also fail second-line treatment.

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, including pain, for which there are limited existing treatment options. Axsome's product candidate portfolio includes two late-stage candidates, AXS-02 and AXS-05. AXS-02 is currently in a Phase 3 trial in complex regional pain syndrome (CRPS) with additional Phase 3 trials planned in knee osteoarthritis (OA) associated with bone marrow lesions (BMLs) and chronic low back pain (CLBP) associated with Modic changes (MCs). AXS-05 is currently in a Phase 3 trial in treatment resistant depression (TRD). AXS-02 and AXS-05 are investigational 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; 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

Trout Group Contact:
Marcy Beth Nanus
Senior Vice President

The Trout Group LLC
Tel: 646-378-2927
Email: mnanus@troutgroup.com

Axsome Therapeutics, Inc.