Axsome Therapeutics, Inc. Logo

Axsome Therapeutics Initiates Phase 2 Trial of AXS-05 in Major Depressive Disorder

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First patient enrolled in the ASCEND study

Trials in two mood disorders now underway with AXS-05

NEW YORK, June 05, 2018 (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 ASCEND (Assessing Clinical Episodes in Depression) study, a Phase 2 randomized, controlled trial of AXS-05 in major depressive disorder (MDD). AXS-05 is a novel, oral, glutamatergic and monoaminergic investigational medicine consisting of dextromethorphan and bupropion. Topline results from the ASCEND trial are expected in the second half of 2018.

AXS-05 is now being evaluated in two mood disorder clinical programs—MDD with the ASCEND Phase 2 trial, and treatment resistant depression (TRD) with the ongoing STRIDE-1 Phase 3 trial. MDD is characterized by consistently depressed mood that impairs functioning. Patients diagnosed with MDD are defined as having TRD if they have failed to respond to two or more antidepressant therapies.

“Axsome is committed to addressing the urgent need for new treatment options for the millions of patients living with depression,” said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. “AXS-05 features multiple novel mechanisms of action which, along with the recent positive interim futility analysis of the Phase 3 trial in TRD, support its evaluation in the broader MDD population. AXS-05 is now being studied in four clinical trials across four indications. We look forward to a busy second half of 2018 for AXS-05, with anticipated topline results from the Phase 2 ASCEND trial in MDD, the first interim analysis of the Phase 2/3 ADVANCE-1 trial in Alzheimer’s disease agitation, and the next and final interim analysis for efficacy of the Phase 3 STRIDE-1 trial in TRD.”

About the ASCEND Study

ASCEND (Assessing Clinical Episodes in Depression) is a Phase 2, double-blind, randomized, active-controlled, multicenter trial of AXS-05 in patients with MDD. Approximately 74 patients will be randomized in a 1:1 ratio to receive AXS-05 or bupropion for 6 weeks. Assessments that will be conducted throughout the study include safety parameters, the Montgomery-Åsberg Depression Rating Scale (MADRS), other clinician-rated scales, as well as patient-reported outcome measures.

About Major Depressive Disorder (MDD)

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, or approximately 16 million, 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. Patients diagnosed with MDD are defined as having treatment resistant depression (TRD) if they have failed to respond to two or more antidepressant therapies.

About AXS-05

AXS-05 is a novel, oral, investigational drug product under development for the treatment of central nervous system (CNS) disorders. AXS-05 consists of bupropion and dextromethorphan and utilizes Axsome’s metabolic inhibition technology. Dextromethorphan is an NMDA receptor antagonist, sigma-1 receptor agonist, nicotinic acetylcholine receptor antagonist, and inhibitor of the serotonin and norepinephrine transporters. Bupropion serves to increase the bioavailability of dextromethorphan, and is a norepinephrine and dopamine reuptake inhibitor, and a nicotinic acetylcholine receptor antagonist. AXS-05 is not approved by the FDA.

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 five clinical-stage candidates, AXS-02, AXS-05, AXS-06, AXS-07, and AXS-09. AXS-05 is currently in a Phase 3 trial in treatment resistant depression (TRD), a Phase 2/3 trial in agitation associated with Alzheimer’s disease (AD), a Phase 2 trial in Major Depressive Disorder (MDD), and a Phase 2 trial in smoking cessation. AXS-02 is currently in a Phase 3 trial in 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). AXS-07 is being developed for the acute treatment of migraine. AXS-06 is being developed for the treatment of osteoarthritis and rheumatoid arthritis and for the reduction of the risk of NSAID-associated gastric ulcers. AXS-02, AXS-05, AXS-06, AXS-07, and AXS-09 are investigational drug products not approved by the FDA. For more information, please visit the Company’s website at 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, interim analyses 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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