Axsome Therapeutics to Present Data on AXS-05 at the 2018 American Society of Clinical Psychopharmacology Annual Meeting

May 29, 2018

NEW YORK, May 29, 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, today announced that Phase 1 pharmacokinetic and mechanism of action data and analyses for AXS-05, its novel glutamatergic and monoaminergic product candidate, will be presented at the 2018 Annual Meeting of the American Society of Clinical Psychopharmacology (ASCP) on May 31, 2018 in Miami, FL.

Analyses will be presented demonstrating similarities between AXS-05 and the potent and fast-acting antidepressant ketamine, based on mechanisms of action and functional animal data. Data from a Phase 1 pharmacokinetic trial of AXS-05 will also be presented along with analyses showing attainment of drug levels that target CNS receptors relevant to neuropsychiatric disorders. AXS-05 is currently being evaluated in a Phase 3 trial in treatment resistant depression, a Phase 2/3 trial in agitation associated with Alzheimer's disease, and a Phase 2 trial in smoking cessation.

Below are the details of the presentation, which will be given by Cedric O'Gorman, M.D., Senior Vice President, Clinical Development and Medical Affairs of Axsome:

Poster Presentation:
Title: AXS-05 for Neuropsychiatric Disorders: Scientific Rationale and Clinical Development
Poster Number: T16
Date: Thursday, May 31, 2018
Time:12:30 PM – 2:00 PM Eastern Time

AXS-05 combines monoamine, glutamatergic and anti-inflammatory mechanisms of action. The biological pathways targeted by these pharmacological actions have been implicated in depressive disorders and in the neuropsychiatric symptoms of Alzheimer's disease.

A copy of the poster will be available shortly after the meeting on Axsome's website at www.axsome.com.

About AXS-05

AXS-05 is a novel, oral, investigational medicine 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), 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 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". The Company 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 the Company's ongoing clinical trials and anticipated clinical trials for its current product candidates, including statements regarding the timing of initiation, interim analyses and completion of the trials; the timing of and the Company's ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, its 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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