Axsome Therapeutics Presents Scientific Rationale for the Development of AXS-05 at the 20th Annual Meeting of the American Society for Experimental Neurotherapeutics

March 12, 2018

NEW YORK, March 12, 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 presentations on AXS-05, its novel glutamatergic and monoaminergic product candidate, at the 20th annual meeting of the American Society for Experimental Neurotherapeutics (ASENT), held in Rockville, MD, March 7-10, 2018.

Axsome delivered three presentations, two oral and one poster, during the conference. These presentations reviewed the mechanistic rationale, pharmacokinetic data, and functional clinical data which form the scientific basis for the ongoing Phase 3 trial of AXS-05 in treatment resistant depression, and for the ongoing Phase 2/3 trial of AXS-05 in agitation associated with Alzheimer's disease.

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

Oral Presentations:
Title: The Clinical Development and Therapeutic Potential of AXS-05 for Neuropsychiatric Disorders
Session: Pipeline Presentations

Title: The Clinical Development and Therapeutic Potential of AXS-05 for the Neuropsychiatric Symptoms of Alzheimer's Disease
Session: Emerging Therapies: Alzheimer's Disease

Poster Presentation:
Title: The Clinical Development and Therapeutic Potential of AXS-05 for Neuropsychiatric Disorders
Poster Number: 13

The mechanisms of action of AXS-05 include NMDA receptor antagonism and sigma-1 receptor agonism. These glutamatergic pathways have been implicated in the pathology of the neuropsychiatric symptoms of Alzheimer's disease. Effects of AXS-05 on monamine reuptake combined with its glutamatergic mechanisms may contribute to antidepressant effects. Pharmacokinetic data with AXS-05 and clinical observations with dextromethorphan indicate that AXS-05 increases dextromethorphan concentrations into a potentially therapeutic range.

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

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) and a Phase 2/3 trial in agitation associated with Alzheimer's disease (AD). AXS-05 is also being developed for 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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