# Axsome Therapeutics Announces Completion of Patient Enrollment in the ASCEND Phase 2 Trial of AXS-05 in Major Depressive Disorder

November 14, 2018

NEW YORK, Nov. 14, 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 the completion of patient enrollment 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, investigational medicine, consisting of dextromethorphan and bupropion, with glutamatergic, monoaminergic, and anti-inflammatory mechanisms. Topline results from the ASCEND trial are expected early January 2019.

"We are excited to complete enrollment of the ASCEND trial, and we look forward to the upcoming results of this study. ASCEND is evaluating the effect of AXS-05 as compared to bupropion on the symptoms of major depressive disorder," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. "We believe that the multiple mechanisms of action of AXS-05 may be relevant to other CNS disorders. In addition to major depressive disorder, we are also evaluating AXS-05 in treatment resistant depression with the ongoing STRIDE-1 Phase 3 trial, agitation associated with Alzheimer's disease with the ongoing ADVANCE-1 Phase 2/3 trial, and smoking cessation with a Phase 2 trial that is being conducted under a research collaboration with Duke University."

**About the ASCEND Study**

ASCEND (Assessing Clinical Episodes in Depression) is a Phase 2, randomized, double-blind, 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 Institutes 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 core CNS product candidate portfolio includes four clinical-stage candidates, AXS-05, AXS-07, AXS-09, and AXS-12. 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-07 is being developed for the acute treatment of migraine. AXS-12 is being developed for the treatment of the symptoms of narcolepsy. The Axsome Pain and Primary Care business unit (Axsome PPC) houses Axsome's pain and primary care assets, including AXS-02 and AXS-06, and intellectual property which covers these and related product candidates and molecules being developed by Axsome and others. AXS-02 is being developed for osteoporosis, the pain of knee osteoarthritis, and chronic low back pain. AXS-06 is being developed for osteoarthritis and rheumatoid arthritis. AXS-02, AXS-05, AXS-06, AXS-07, AXS-09, and AXS-12 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". 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, futility analyses and receipt of interim results, which are not necessarily indicative of the final results of the Company's ongoing clinical trials; the Company's ability to fund additional clinical trials to continue the advancement of its product candidates; 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 expected cash runway; 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
Senior 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

Source: Axsome Therapeutics, Inc.