Axsome Therapeutics Announces AXS-07 Phase 3 Migraine Trial Results Selected by the American Academy of Neurology Science Committee as Featured Presentation

September 17, 2020

Data from MOMENTUM Phase 3 trial to be presented at the 2020 AAN Science Highlights Platform

NEW YORK, Sept. 17, 2020 (GLOBE NEWSWIRE) -- Axsome Therapeutics, Inc. (NASDAQ: AXSM), a biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders, today announced that Phase 3 data for AXS-07 in the acute treatment of migraine has been selected as a featured presentation at the 2020 American Academy of Neurology (AAN) Science Highlights platform, to be held virtually September 23, 2020 at 12:15 PM Central Time. AXS-07 (MoSEIC™ meloxicam/rizatriptan) is Axsome's novel, oral, multi-mechanistic investigational medicine for the acute treatment of migraine. The presentation will highlight new insights from the Phase 3 MOMENTUM trial of AXS-07, and will be followed with live Q&A.

The AAN Science Committee reviewed over 150 late-breaking, or Emerging Science, abstracts and selected 12 to be featured presentations on the new 2020 AAN Science Highlights platform. The results of the Phase 3 MOMENTUM trial were one of the 12 selected abstracts. According to the AAN, the selected abstracts contain timely, significant, and innovative content.

Details of the presentation are as follows:

Title: Efficacy and Safety of AXS-07 for the Acute Treatment of Migraine: Results from the MOMENTUM (Maximizing Outcomes in Treating Acute Migraine) Phase 3 Randomized, Double-blind, Active- and Placebo-controlled Study
Session: Emerging Science: Alzheimer's, Migraine, ALS and CIDP
Date: Wednesday September 23, 2020
Time: 12:15 – 12:30 PM Central Time
Location: The 2020 AAN Science Highlights virtual platform will be available to everyone. Attendees will be asked to register to access the session at: https://www.aan.com/education-and-research/research/2020-aan-science-highlights/. A recording of the webinar will be available on the AAN Science Highlights platform following the session.

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

About AXS-07

AXS-07 is a novel, oral, multi-mechanistic, investigational medicine under development for the acute treatment of migraine. AXS-07 consists of MoSEIC™ meloxicam and rizatriptan. Meloxicam is a new molecular entity for migraine enabled by Axsome's MoSEIC (Molecular Solubility Enhanced Inclusion Complex) technology, which results in rapid absorption of meloxicam while maintaining a long plasma half-life. Meloxicam is a COX-2 preferential non-steroidal anti-inflammatory drug and rizatriptan is a 5-HT1B/1D agonist. AXS-07 is designed to provide rapid, enhanced and consistent relief of migraine, with reduced symptom recurrence. AXS-07 is not approved by the FDA.

About Axsome Therapeutics, Inc.

Axsome Therapeutics, Inc. is a biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders for which there are limited treatment options. For the many people facing unsatisfactory treatments for CNS disorders, Axsome accelerates the invention and adoption of life-changing medicines. Axsome's core CNS product candidate portfolio includes five clinical-stage candidates, AXS-05, AXS-07, AXS-09, AXS-12, and AXS-14. AXS-05 is being developed for major depressive disorder (MDD), treatment resistant depression (TRD), Alzheimer's disease (AD) agitation, and as a treatment for smoking cessation. AXS-07 is being developed for the acute treatment of migraine. AXS-12 is being developed for the treatment of narcolepsy. AXS-14 is being developed for fibromyalgia. AXS-05, AXS-07, AXS-09, AXS-12, and AXS-14 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, pace of enrollment and completion of the trials (including our ability to fully fund our disclosed clinical trials, which assumes no material changes to our currently projected expenses), futility analyses and receipt of interim results, which are not necessarily indicative of the final results of our ongoing clinical trials, and the number or type of studies or nature of results necessary to support the filing of a new drug application ("NDA") for any of our current product candidates; our ability to fund additional clinical trials to continue the

advancement of our product candidates; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration ("FDA") or other regulatory authority approval of, or other action with respect to, our product candidates (including, but not limited to, FDA's agreement with the Company's discontinuation of the bupropion treatment arm of the ADVANCE-1 study in accordance with the independent data monitoring committee's recommendations); the potential for the MOMENTUM clinical trial to provide a basis for approval of AXS-07 for the acute treatment of migraine in adults with or without aura, pursuant to our special protocol assessment; the potential for the ASCEND clinical trial, combined with the GEMINI clinical trial results, to provide a basis for approval of AXS-05 for the treatment of major depressive disorder and accelerate its development timeline and commercial path to patients; 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; the Company's anticipated capital requirements, including the Company's anticipated cash runway; unforeseen circumstances or other disruptions to normal business operations arising from or related to COVID-19; 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
Chief Operating Officer
Axsome Therapeutics, Inc.
22 Cortlandt Street, 16th Floor
New York, NY 10007
Tel: 212-332-3243
Email: mjacobson@axsome.com
www.axsome.com

Source: Axsome Therapeutics, Inc.