Axsome Therapeutics to Host Investor R&D Call with Key Opinion Leaders Focusing on AXS-07 and the Unmet Needs in the Acute Treatment of Migraine

November 21, 2019

Company to host conference call on Monday, November 25 at 9:00 AM Eastern

NEW YORK, Nov. 21, 2019 (GLOBE NEWSWIRE) -- Axsome Therapeutics, Inc. (NASDAQ: AXSM), a clinical-stage biopharmaceutical company developing novel therapies for the management of central nervous system (CNS) disorders, is hosting an R&D conference call and webcast with slides on Monday, November 25, 2019 at 9:00 AM Eastern Time with key opinion leaders (KOLs) focusing on AXS-07 (MoSEIC™ meloxicam/rizatriptan) and the unmet needs in the acute treatment of migraine. AXS-07 is being evaluated in the ongoing MOMENTUM Phase 3 trial in migraine patients with a history of inadequate response to prior acute treatments, with topline results expected in the fourth quarter of 2019.

The investor call will feature presentations from **Dr. Stewart J. Tepper**, Professor of Neurology at The Geisel School of Medicine at Dartmouth; and **Dr. Richard B. Lipton**, Professor and Vice Chair of Neurology, and Director of the Montefiore Headache Center, at the Albert Einstein College of Medicine. The call will also include presentations and discussion from Axsome management. Dr. Tepper, Dr. Lipton and Axsome's management team will be available to answer questions following the presentations.

Agenda

- Introductions – Mark Jacobson, Senior Vice President, Operations
- Welcome – Dr. Herriot Tabuteau, Chief Executive Officer
- Migraine: Multiple Mechanisms of Disease, Treatment Targets and the Potential for AXS-07 – Dr. Stewart Tepper
- Inadequate Response to Acute Migraine Treatment – Dr. Richard Lipton
- Update on the Clinical Development of AXS-07 – Dr. Cedric O'Gorman, Senior Vice President, Clinical Development and Medical Affairs
- MINDSET Physician Survey informs Market Opportunity – Dave Marek, Chief Commercial Officer
- Panel Discussion and General Q&A

To participate in the live conference call, please dial (844) 698-4029 (toll-free domestic) or (647) 253-8660 (international) and use the passcode 5175238. A live and archived webcast of the call, with slides, can be accessed on the "Webcasts & Presentations" page of the "Investors" section of the Company's website at axsome.com.

KOL Credentials

Stewart J. Tepper, M.D., is Professor of Neurology at the Geisel School of Medicine at Dartmouth. He is Director of the Dartmouth Headache Center in the Department of Neurology of Dartmouth-Hitchcock Medical Center. Dr. Tepper has been Co-Director of the Scottsdale Headache Symposium course of the American Headache Society since 2008 and was director of the Headache Therapy course for the American Academy of Neurology from 2009 to 2011. Dr. Tepper is Editor-in-Chief of the journal Headache Currents and Associate Editor for the journal Headache. He has published more than 350 peer-reviewed manuscripts, editorials, and books. He serves on the Board of Directors of the American Headache Society.

Richard B. Lipton, M.D., is the Edwin S. Lowe Professor and Vice Chair of Neurology, and Director of the Montefiore Headache Center, at the Albert Einstein College of Medicine. He is a diplomate of the American Board of Psychiatry and Neurology and a fellow of the American Academy of Neurology. Dr. Lipton has written 11 books, published more than 800 original articles and is a five-time winner of the H.G. Wolff Award for excellence in headache research from the American Headache Society and a two-time winner of the Enrico Greppi award from the European Headache Federation. Dr. Lipton holds leadership positions in several professional societies and is Past President of the American Headache Society (AHS). Dr. Lipton also serves on the editorial boards of several journals, including Neurology.

About Migraine

Over 37 million Americans suffer from migraine according to the Centers for Disease Control, and it is the leading cause of disability among neurological disorders in the United States according to the American Migraine Foundation. Migraine is characterized by recurrent attacks of pulsating, often severe and disabling head pain associated with nausea, and sensitivity to light and or sound. It is estimated that migraine accounts for $78 billion in direct (e.g. doctor visits, medications) and indirect (e.g. missed work, lost productivity) costs each year in the United States [1]. Published surveys of migraine sufferers indicate that more than 70% are not fully satisfied with their current treatment, that nearly 80% would try a new therapy, and that they desire treatments that work faster, more consistently, and result in less symptom recurrence [2,3].

About AXS-07

AXS-07 is a novel, oral, investigational medicine with distinct dual mechanisms of action 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-$HT_{1B/1D}$ 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 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 3 trial in major depressive disorder (MDD), and a Phase 2/3 trial in agitation associated with Alzheimer's disease (AD). AXS-05 is also being developed for smoking cessation treatment. AXS-07 is currently in two Phase 3 trials for the acute treatment of migraine. AXS-12 is currently in a Phase 2 trial in narcolepsy. AXS-05, 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.

References

1. Gooch CL, Pracht E, Borenstein AR. The burden of neurological disease in the United States: A summary report and call to action. Ann Neurol. 2017 Apr; 81(4):479-484.

2. Smelt AF, Louter MA, Kies DA, Blom JW, Terwindt GM, van der Heijden GJ, De Gucht V, Ferrari MD, Assendelft WJ. What do patients consider to be the most important outcomes for effectiveness studies on migraine treatment? Results of a Delphi study. PLoS One. 2014 Jun 16;9(6):e98933.

3. Lipton RB, Stewart WF. Acute migraine therapy: do doctors understand what patients with migraine want from therapy? Headache. 1999;39(suppl 2):S20-S26.

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 plan to discontinue the bupropion treatment arm of the ADVANCE-1 study in accordance with the independent data monitoring committee's recommendations); the potential for the ASCEND clinical trial 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 and the Company's current expectations regarding its plans for future equity financings prior to the readout from its Phase 3 trials; 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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Source: Axsome Therapeutics, Inc.