Axsome Therapeutics Announces Publication of Research Showing AXS-02 Inhibits Pain in Animal Model of Complex Regional Pain Syndrome

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NEW YORK, Oct. 04, 2016 (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 publication of data showing that AXS-02 (oral zoledronate) inhibits pain in a well-validated animal model of complex regional pain syndrome (CRPS).

The study, conducted by researchers at the Veterans Affairs Palo Alto Health Care System and Stanford University School of Medicine, examined the effect of oral zoledronate on pain behavior in the rat tibia fracture model of CRPS. The study was published in the October 2016 issue of *Anesthesia & Analgesia*, a peer-reviewed medical journal. A link to the article abstract can be accessed on PubMed at:

https://www.ncbi.nlm.nih.gov/pubmed/27636578

Results of the study revealed that oral zoledronate (AXS-02) completely reversed established pain and improved weight bearing in the rat tibia fracture model of CRPS. Oral zoledronate also prevented the development of pain when administration was started at the time of fracture.

AXS-02 is currently in Phase 3 trials for the treatment of the pain of CRPS (the CREATE-1 trial), and the pain of knee osteoarthritis associated with bone marrow lesions (the COAST-1 trial).

About Complex Regional Pain Syndrome

Complex regional pain syndrome (CRPS) is a debilitating condition characterized by severe, continuous, burning or throbbing pain in a limb. The excessive pain is accompanied by changes in skin color, temperature and/or swelling. It is considered to be one of the most painful conditions, results in loss of physical function, and can lead to significant and sometimes permanent disability. There is currently no medication approved for the treatment of CRPS.

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, including pain, for which there are limited existing treatment options. Axsome's product candidate portfolio includes two late-stage candidates, AXS-02 and AXS-05. AXS-02 is currently in Phase 3 trials in complex regional pain syndrome (CRPS) and 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-05 is currently in a Phase 3 trial in treatment resistant depression (TRD), and a Phase 2/3 trial in agitation in patients with Alzheimer's disease (AD) is planned. AXS-02 and AXS-05 are investigational product candidates 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". 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 and completion of the trials; the timing of and

our ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, our 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.

Axsome Contact:
Mark Jacobson
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

Trout Group Contact:
Marcy Beth Nanus
Senior Vice President
The Trout Group LLC
Tel: 646-378-2927
Email: mnanus@troutgroup.com

Axsome Therapeutics, Inc.