Axsome Therapeutics Announces Issuance of U.S. Patent Covering AXS-02 for the Treatment of Bone Marrow Lesions of the Knee

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- Provides Patent Protection into 2033

NEW YORK, Jan. 27, 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 that the U.S. Patent and Trademark Office has issued a patent (U.S. Patent No. 9,211,257), which provides coverage for AXS-02, one of Axsome's late-stage product candidates. The patented claims cover the use of zoledronic acid, the active moiety in AXS-02, for the treatment of bone marrow lesions (BMLs) of the knee. AXS-02 is in development for the pain of knee osteoarthritis associated with BMLs. The term of the issued patent extends into 2033.

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. Axsome's product candidate portfolio includes two late-stage candidates, AXS-02 and AXS-05. AXS-02 is currently in a Phase 3 trial in complex regional pain syndrome (CRPS), with additional Phase 3 trials planned in knee osteoarthritis (OA) associated with bone marrow lesions (BMLs), and chronic low back pain (CLBP) associated with Modic changes (MCs). A Phase 3 trial in treatment resistant depression (TRD) is currently planned with AXS-05.

AXS-02 and AXS-05 are investigational medications not approved by the FDA. The safety and efficacy of AXS-02 and AXS-05 have not yet been established.

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.

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