Axsome Therapeutics Receives New U.S. Patent Covering AXS-02 for the Treatment of Complex Regional Pain Syndrome

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- Provides Patent Protection for AXS-02 into 2033
- Covers Uses of Oral Zoledronic Acid for Complex Regional Pain Syndrome
- Represents the 19th Issued Patent Covering AXS-02 or Related Compounds

NEW YORK, March 15, 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, received a new patent (U.S. Patent No. 9,283,239), titled “Compositions for Oral Administration of Zoledronic Acid or Related Compounds for Treating Complex Regional Pain Syndrome”, from the U.S. Patent and Trademark Office. The patent provides intellectual property protection for AXS-02 (disodium zoledronate tetrahydrate), which is currently in development for the treatment of complex regional pain syndrome (CRPS).

The patented claims cover uses of oral zoledronic acid, the active moiety in AXS-02, for the treatment of CRPS. Another patent covering uses of oral zoledronic acid for the treatment of CRPS (U.S. Patent No. 9,216,168) was issued in December 2015 and provides additional protection. The terms of these issued patents extend into 2033 and 2034, respectively. These patents are part of a portfolio of 19 issued patents covering AXS-02, other bisphosphonates or other osteoclast inhibitors. AXS-02 is a potent osteoclast inhibitor developed by Axsome as an oral, targeted, non-opioid, potentially first-in-class therapeutic for chronic pain, including pain associated with CRPS.

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.

Axsome is currently conducting a Phase 3 trial, named the CREATE-1 study, of AXS-02 in patients with CRPS. This global trial is enrolling patients in the United States, the United Kingdom, Australia and Canada. AXS-02 has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of pain associated with CRPS. AXS-02 has also been granted Orphan Drug Designation by the FDA and Orphan Medicinal Product Designation by the European Medicines Association (EMA) for the treatment of CRPS.

About the CREATE-1 Study

CREATE-1 (CRPS Treatment Evaluation 1 Study) is a Phase 3 multinational, multicenter, randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy and safety of AXS-02 for the treatment of pain associated with CRPS. The study is expected to enroll approximately 190 patients at sites in the United States, Canada, the United Kingdom and Australia. Eligible patients must be at least 18 years of age with recently diagnosed CRPS type 1 related to a traumatic injury. Eligible patients will be randomized in a 1:1 ratio to be receive either AXS-02 or placebo by mouth once weekly for six weeks. The primary efficacy measure is the change in patient-reported pain intensity at the end of Week 12. Secondary outcome measures include assessments of the change in the Brief Pain Inventory (BPI) score, Patient and Clinician Global Impression of Change (PGI-C and CGI-C, respectively) and other quality-of-life measures.

To learn about eligibility, patients can visit www.CRPStrial.com.

More information about the CREATE-1 study is available at www.clinicaltrials.gov.

About AXS-02

AXS-02 (disodium zoledronate tetrahydrate) is a potent osteoclast inhibitor being developed as an oral, targeted, non-opioid, potentially first-in-class therapeutic for chronic pain, including pain associated with CRPS. AXS-02 has been granted Fast Track designation by the FDA for the treatment of pain associated with CRPS. AXS-02 has also been granted Orphan Drug Designation by the FDA and Orphan Medicinal Product Designation by the EMA for the treatment of CRPS. AXS-02 is an investigational product not approved by the FDA.

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).

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 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 products 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.