Axsome Therapeutics Announces FDA Fast Track Designation for AXS-02 for the Treatment of Pain Associated With Complex Regional Pain Syndrome

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NEW YORK, March 5, 2015 (GLOBE NEWSWIRE) — Axsome Therapeutics, Inc. today announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for AXS-02 for the treatment of pain associated with complex regional pain syndrome (CRPS). AXS- 02 is an oral, non-opioid, potentially first-in-class pain therapeutic being developed by Axsome for the treatment of chronic pain caused by CRPS.

CRPS is a debilitating condition characterized by severe pain in a limb, accompanied by autonomic, sensory, motor and trophic changes. For many patients, the pain and associated loss of function result in significant and sometimes permanent disability. There is currently no drug approved to treat this orphan condition in either the United States or the European Union.

“We are pleased that the FDA has granted Fast Track status for AXS-02 for the treatment of pain associated with CRPS, as it demonstrates their recognition of this condition as a significant unmet medical need,” said Herriot Tabuteau, M.D., Chief Executive Officer of Axsome. “Our product’s Fast Track designation status, in addition to Orphan Drug designations from both the FDA and EMA [European Medicines Agency], provide significant regulatory confirmation as we work to bring our therapy to those suffering from this serious condition.”

The FDA’s Fast Track designation program is designed to aid in the development and expedite the review of drugs that are intended to treat serious or life-threatening conditions. In order to receive Fast Track designation, a product must also demonstrate the potential to address an unmet medical need. Fast Track designation provides greater access to, and more frequent communication with, the FDA throughout the entire drug development and review process, with the goal of getting important new drugs to patients more rapidly. It also provides the opportunity to submit sections of a New Drug Application (NDA) on a rolling basis, where the FDA may review portions of the NDA as they are received instead of waiting for the entire NDA submission. In addition, Fast Track designated products are eligible for Priority Review at the time of NDA submission.

AXS-02 Previously Granted Orphan Drug Designations in the U.S. and E.U.
Previously, 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.

Orphan Drug Designation is granted by the FDA Office of Orphan Drug Products to novel drugs intended to treat rare diseases, defined as those affecting fewer than 200,000 people in the U.S. This designation may entitle Axsome to a period of seven years of marketing exclusivity in the U.S. upon FDA approval. Orphan Drug Designation also confers special incentives to Axsome including tax credits towards the cost of clinical trials and a waiver of the Company’s obligation to pay the FDA application user fees for the product as required by the Prescription Drug User Fee Act.

The EMA’s Orphan Medicinal Product Designation is designed to encourage the development of drugs that may provide significant benefit to patients suffering from rare diseases identified as life-threatening or chronically debilitating. Designation provides ten years of potential market exclusivity in the European Union if the product candidate is approved and the orphan designation is maintained. Orphan status also permits EMA assistance in optimizing the candidate’s clinical development through participation in designing the clinical protocol and preparing the marketing application. Additionally, a drug candidate designated by the EMA as an Orphan Medicinal Product may qualify for a reduction in regulatory fees as well as a European Union-funded research grant. Finally, if a Pediatric Investigation Plan is completed, an additional two years of exclusivity could be granted for a product with Orphan Medicinal Product Designation.
About Axsome Therapeutics, Inc.

Axsome Therapeutics, Inc. is a biopharmaceutical company developing novel therapies for the management of pain and

other neurological disorders.

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