Axsome Therapeutics Initiates FORWARD Phase 3 Trial of AXS-14 for the Management of Fibromyalgia

January 15, 2026

NEW YORK, Jan. 15, 2026 (GLOBE NEWSWIRE) -- Axsome Therapeutics, Inc. (NASDAQ: AXSM), a biopharmaceutical company leading a new era in the treatment of central nervous system (CNS) disorders, today announced the first patient has been dosed in the FORWARD Phase 3 trial of AXS-14 (esreboxetine) for the management of fibromyalgia.

FORWARD (Fibromyalgia Response with Esreboxetine Evaluated Using a Randomized Withdrawal Research Design) is a Phase 3, double-blind, placebo-controlled, multicenter, randomized withdrawal trial in patients with fibromyalgia consisting of an open-label AXS-14 treatment period and a randomized, double-blind treatment period. Patients achieving a treatment response during the 12-week open-label period will be randomized in a 1:1 ratio to continue AXS-14 (8 mg) once daily or to switch to matching placebo for up to 12 weeks or until a loss of therapeutic response occurs. The primary endpoint will be the time from randomization to loss of therapeutic response.

About Fibromyalgia

Fibromyalgia is a chronic, debilitating neurological pain disorder that affects approximately 17 million people in the U.S.[1,2] Fibromyalgia is considered to be mediated mainly in the central nervous system.[2] It is characterized by widespread pain, fatigue, disturbed sleep, depression, cognitive impairment, and hypersensitivity to sensory stimuli.[1,2] Other symptoms of this disorder can include tingling in the hands and feet and headaches.[2-4] Fibromyalgia has considerable detrimental effects on physical, emotional, social, and day-to-day functioning and is associated with significant economic burden and reduced quality of life.[5] Despite its prevalence and impact, current treatment options remain limited. Many patients experience inadequate symptom control or intolerable side effects, with over 50% of fibromyalgia patients discontinuing their treatment within the first year.[6]

About AXS-14

AXS-14 (esreboxetine) is a highly selective and potent norepinephrine reuptake inhibitor being developed for the management of fibromyalgia. Esreboxetine is the SS-enantiomer of racemic reboxetine. AXS-14 is an investigational drug product not approved by the FDA.

About Axsome Therapeutics

Axsome Therapeutics is a biopharmaceutical company leading a new era in the treatment of central nervous system (CNS) conditions. We deliver scientific breakthroughs by identifying critical gaps in care and develop differentiated products with a focus on novel mechanisms of action that enable meaningful advancements in patient outcomes. Our industry-leading neuroscience portfolio includes FDA-approved treatments for major depressive disorder, excessive daytime sleepiness associated with narcolepsy and obstructive sleep apnea, and migraine, and multiple late-stage development programs addressing a broad range of serious neurological and psychiatric conditions that impact over 150 million people in the United States. Together, we are on a mission to solve some of the brain's biggest problems so patients and their loved ones can flourish. For more information, please visit us at www.axsome.com and follow us on LinkedIn and X.

Forward Looking Statements

Certain matters discussed in this press release are "forward-looking statements". The Company 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 commercial success of the Company's SUNOSI ®, AUVELITY®, and SYMBRAVO® products and the success of the Company's efforts to obtain any additional indication(s) with respect to solriamfetol and/or AXS-05; the Company's ability to maintain and expand payer coverage; the success, timing and cost of the Company's ongoing clinical trials and anticipated clinical trials for the Company's current product candidates, including statements regarding the timing of initiation, pace of enrollment and completion of the trials (including the Company's ability to fully fund the Company's disclosed clinical trials, which assumes no material changes to the Company's currently projected revenues or expenses), futility analyses and receipt of interim results, which are not necessarily indicative of the final results of the Company's ongoing clinical trials, and/or data readouts, 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 the Company's current product candidates; the Company's ability to fund additional clinical trials to continue the advancement of the Company's product candidates; the timing of and the Company's ability to obtain and maintain U.S. Food and Drug Administration ("FDA") or other regulatory authority approval of, or other action with respect to, the Company's product candidates, including statements regarding the timing of any NDA submission; 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 Company's ability to successfully resolve any intellectual property litigation, and even if such disputes are settled, whether the applicable federal agencies will approve of such settlements; 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 products and product candidates, if approved; the Company's anticipated capital requirements, including the amount of capital required for the commercialization of SUNOSI, AUVELITY, and SYMBRAVO and for the Company's commercial launch of its other product candidates, if approved, and the potential impact on the Company's anticipated cash runway; the Company's ability to convert sales to recognized revenue and maintain a favorable gross to net sales; unforeseen circumstances or other disruptions to normal business operations arising from or related to domestic political climate, geo-political conflicts or a global pandemic 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 circumstances.

Investors:
Ashley Dong
Director, Investor Relations
(929) 687-1614
adong@axsome.com

Media:
Darren Opland
Senior Director, Corporate Communications
(929) 837-1065
dopland@axsome.com

References:

1. Vincent A, et al. Prevalence of fibromyalgia: a population-based study in Olmsted County, Minnesota, utilizing the Rochester Epidemiology Project. Arthritis Care Res (Hoboken). 2013 May;65(5):786-92. https://pubmed.ncbi.nlm.nih.gov/23203795/

2. Clauw DJ. Fibromyalgia: a clinical review. JAMA. 2014 Apr 16;311(15):1547-55. https://pubmed.ncbi.nlm.nih.gov/24737367/

3. Clauw DJ. From fibrositis to fibromyalgia to nociplastic pain: how rheumatology helped get us here and where do we go from here? Ann Rheum Dis. 2024 Oct 21;83(11):1421-1427. https://pubmed.ncbi.nlm.nih.gov/39107083/

4. Bair MJ and Krebs EE. Fibromyalgia. Ann Intern Med. 2020;172:ITC33-ITC48. https://pubmed.ncbi.nlm.nih.gov/32120395/

5. Arnold LM, et al. Patient Perspectives on the Impact of Fibromyalgia. Patient Educ Couns. 2008 Oct;73(1):114-20. https://pubmed.ncbi.nlm.nih.gov/18640807/

6. Liu Y, et al. Treatment Patterns Associated with ACR-Recommended Medications in the Management of Fibromyalgia in the United States. J Manag Care Spec Pharm. 2016 Mar;22(3):263-71. https://pubmed.ncbi.nlm.nih.gov/27003556/

Source: Axsome Therapeutics, Inc.