Axsome Therapeutics Initiates ENGAGE Phase 3 Trial of Solriamfetol for the Treatment of Binge Eating Disorder

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NEW YORK, April 01, 2024 (GLOBE NEWSWIRE) -- Axsome Therapeutics, Inc. (NASDAQ: AXSM), a biopharmaceutical company developing and delivering novel therapies for the management of central nervous system (CNS) disorders, announced the initiation of the ENGAGE Phase 3 trial of solriamfetol, an investigational treatment for binge eating disorder (BED) in adults.

ENGAGE (Elucidating TAAR-1, Dopamine, and Norepinephrine in Binge Eating Disorder Using Solriamfetol) is a Phase 3, randomized, double-blind, placebo-controlled, multicenter trial to assess the efficacy and safety of solriamfetol for the treatment of BED in adults. Approximately 450 patients will be randomized in a 1:1:1 ratio to receive solriamfetol (150 or 300 mg) or placebo for 12 weeks. The primary endpoint will be the change in binge eating episodes. The first patient was screened in the ENGAGE trial in March 2024.

About Binge Eating Disorder

Binge eating disorder (BED) is a serious, chronic biologically based disorder characterized by recurrent episodes of eating excessive amounts of food within a discrete period of time while also feeling a lack of control over the eating, distress about the bingeing, and without weight-compensatory behaviors seen in bulimia nervosa, such as purging.[1] BED is the most common eating disorder, affecting an estimated 2.8% of U.S. adults, or about 7 million, and it is 1.75 times more common in women.[2]

About Solriamfetol

Solriamfetol is a dopamine and norepinephrine reuptake inhibitor and trace amine-associated receptor 1 (TAAR1) agonist. Solriamfetol is not approved by the FDA for the treatment of binge eating disorder.

About Axsome Therapeutics, Inc.

Axsome Therapeutics, Inc. is a biopharmaceutical company developing and delivering novel therapies for central nervous system (CNS) conditions that have limited treatment options. Through development of therapeutic options with novel mechanisms of action, we are transforming the approach to treating CNS conditions. At Axsome, we are committed to developing products that meaningfully improve the lives of patients and provide new therapeutic options for physicians. For more information, please visit the Company's website at 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 continued commercial success of our Sunosi® and Auvelity® products and the success of our efforts to obtain any additional indication(s) with respect to solriamfetol and/or AXS-05; 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, pace of enrollment and completion of the trials (including our ability to fully fund our disclosed clinical trials, which assumes no material changes to our currently projected revenues or expenses), futility analyses and receipt of interim results, which are not necessarily indicative of the final results of our 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 our current product candidates; our ability to fund additional clinical trials to continue the advancement of our product candidates; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration ("FDA") or other regulatory authority approval of, or other action with respect to, our product candidates, including statements regarding the timing of any NDA submission; whether issues identified by FDA in the complete response letter may impact the potential approvability of the Company's NDA for AXS-07 for the acute treatment of migraine in adults with or without aura, pursuant to our special protocol assessment for the MOMENTUM clinical trial; 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 products and product candidates, if approved; the Company's anticipated capital requirements, including the amount of capital required for the continued commercialization of Sunosi and Auvelity 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; unforeseen circumstances or other disruptions to normal business operations arising from or related to 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 circumstance.

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References:

1. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, 5th ed. Arlington, VA: American Psychiatric Association; 2013.
2. J. I. Hudson, E. Hiripi, H. G. Pope, and R. C. Kessler, “The Prevalence and Correlates of Eating Disorders in the National Comorbidity Survey Replication,” Biol. Psychiatry, vol. 61, no. 3, pp. 348–358, Feb. 2007, doi: 10.1016/j.biopsych.2006.03.040.

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