



Axsome Therapeutics Initiates FOCUS Phase 3 Trial of Solriamfetol for the Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in Adults

July 7, 2023

NEW YORK, July 07, 2023 (GLOBE NEWSWIRE) -- Axsome Therapeutics, Inc. (NASDAQ: AXSM), a biopharmaceutical company developing and delivering novel therapies for the management of central nervous system (CNS) disorders, today announced that it has dosed the first patient in the FOCUS Phase 3 trial of solriamfetol, an investigational treatment for attention deficit hyperactivity disorder (ADHD) in adults.

FOCUS (Forward Treatment of Attention Deficit and Hyperactivity 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 ADHD in adults. Approximately 450 patients will be randomized in a 1:1:1 ratio to receive solriamfetol (150 mg or 300 mg) or placebo for 6 weeks. The primary endpoint will be change in the Adult ADHD Investigator Symptom Report Scale (AISRS).

About Attention Deficit Hyperactivity Disorder (ADHD)

ADHD is a chronic neurobiological and developmental disorder characterized by a persistent pattern of inattention, hyperactivity or impulsivity, that interferes with functioning or development.¹ Impairments in cognition are apparent in attention, planning and problem solving, working memory, and behavioral inhibition.^{2,3} An estimated 11.4 million adults in the U.S. are diagnosed with ADHD, and the condition affects an estimated 5% of children and adolescents.^{4,5} Approximately two-thirds or more of children with ADHD continue to have symptoms and challenges in adulthood.⁶ The total annual societal excess costs associated with adult ADHD in the U.S. have been estimated at \$122.8 billion.⁷

About Solriamfetol

Solriamfetol is a dopamine and norepinephrine reuptake inhibitor. In vitro studies have also shown that solriamfetol has agonist activity at trace amine-associated receptor 1 (TAAR1) and 5HT_{1a} receptors. Solriamfetol is not approved by the FDA for the treatment of ADHD.

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 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; 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 COVID-19; 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 Contacts:

Investors:

Mark Jacobson
Chief Operating Officer
Axsome Therapeutics, Inc.
One World Trade Center, 22nd Floor
New York, NY 10007
Tel: 212-332-3243
Email: mjacobson@axsome.com
www.axsome.com

Media:

Darren Opland
Director, Corporate Communications
Axsome Therapeutics, Inc.
One World Trade Center, 22nd Floor
New York, NY 10007
Tel: 929-837-1065
Email: dopland@axsome.com
www.axsome.com

References:

1. American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders, 5 ed., Arlington, VA: American Psychiatric Publishing, 2013.
2. T. E. Brown, "ADD/ADHD and impaired executive function in clinical practice," Current Psychiatry Reports, vol. 10, p. 407–411, 2008. doi: 10.1037/pne0000271
3. E. Nestler, S. Hyman and R. Malenka, Molecular Neuropharmacology: A Foundation for Clinical Neuroscience, Second Edition, 2nd edition ed., New York: McGraw-Hill Professional, 2008.
4. Faraone, S., Asherson, P., Banaschewski, T. et al. Attention-deficit/hyperactivity disorder. Nat Rev Dis Primers 1, 15020 (2015). <https://doi.org/10.1038/nrdp.2015.20>
5. Kessler RC, et al. The prevalence and correlates of adult ADHD in the United States: results from the National Comorbidity Survey Replication. Am J Psychiatry. 2006 Apr;163(4):716-23. doi: 10.1176/ajp.2006.163.4.716
6. Sibley, MH et al. Variable Patterns of Remission From ADHD in the Multimodal Treatment Study of ADHD. Am J Psychiatry. 2022 Feb;179(2):142-151. doi: 10.1176/appi.ajp.2021.21010032.
7. Schein J, et al. Economic burden of attention-deficit/hyperactivity disorder among adults in the United States: a societal perspective. JMCP. 2022. 28:2, 168-179. doi: 10.18553/jmcp.2021.21290



Source: Axsome Therapeutics, Inc.