Axsome Therapeutics Announces FOCUS Phase 3 Trial of Solriamfetol in Adults with Attention Deficit Hyperactivity Disorder (ADHD) Achieves Primary Endpoint

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Demonstrated substantial and statistically significant improvement in ADHD symptoms as measured by the AISRS total score compared to placebo (p=0.039, primary endpoint, 150 mg solriamfetol)

Statistically significant reduction in overall ADHD disease severity as measured by the CGI-S score compared to placebo (p=0.017, key secondary endpoint, 150 mg solriamfetol)

Statistically significant rate of clinical response on the AISRS compared to placebo (p=0.024, 150 mg solriamfetol)

Onset of action as early as Week 1 compared to placebo (p=0.036, AISRS, 150 mg solriamfetol)

Well tolerated with safety profile generally consistent with prior solriamfetol trials

NEW YORK, March 25, 2025 (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 that the FOCUS Phase 3 trial of solriamfetol in the treatment of attention deficit hyperactivity disorder (ADHD) achieved its primary and key secondary endpoints demonstrating statistically significant improvements in ADHD symptoms and disease severity with solriamfetol compared to placebo. The FOCUS study was a randomized, double-blind, placebo-controlled, multicenter, U.S. trial, in which 516 adults with ADHD were randomized to receive solriamfetol 150 mg, solriamfetol 300 mg, or placebo, once daily, for 6 weeks.

The study achieved the primary endpoint by demonstrating a statistically significant reduction in the Adult ADHD Investigator Symptom Rating Scale (AISRS) total score compared to placebo at Week 6, with mean reductions from baseline of 17.7 points for solriamfetol 150 mg and 14.3 points for placebo (p=0.039). Overall, the improvement with solriamfetol at Week 6 represents a 45% mean reduction from baseline in ADHD symptoms. Improvements in the AISRS total score were greater with solriamfetol compared to placebo starting at Week 1 (p=0.036). Clinical response, defined as ≥30% improvement from baseline in the AISRS total score, was achieved by a statistically significantly greater percentage of patients treated with solriamfetol 150 mg (53.5%) compared to those treated with placebo (41.3%) at Week 6 (p=0.024).

The study also achieved the key secondary endpoint by statistically significantly reducing overall ADHD disease severity compared to placebo, as assessed by the Clinical Global Impression of Severity (CGI-S) for ADHD, at Week 6 (p=0.017). Results on the primary and key secondary endpoints for the exploratory 300 mg solriamfetol dose were numerically superior compared to placebo but were not statistically significant.

Gregory Mattingly, M.D., Associate Clinical Professor of Psychiatry at the Washington University School of Medicine and President of the American Professional Society for ADHD and Related Disorders, commented, “ADHD substantially impairs social, academic, and occupational functioning, while negatively impacting patient quality of life and increasing the risk of morbidity and mortality. The results of the FOCUS trial demonstrate that solriamfetol was able to reduce mean ADHD symptom burden by nearly fifty percent, which contributed to significant reductions in disease severity. These results are especially promising as part of a comprehensive wellness plan for individuals with ADHD. The symptom improvements observed with solriamfetol were accompanied by a favorable safety and tolerability profile. Based on these compelling data, solriamfetol has the potential to be an important new treatment option for adult patients living with ADHD.”

Herriot Tabuteau, MD, Chief Executive Officer of Axsome, said, “We are pleased with the positive results of the FOCUS trial which provide the first evidence from a multicenter controlled trial of the efficacy of solriamfetol in the treatment of ADHD. ADHD is a serious, heterogenous, and prevalent condition. We look forward to advancing the development of solriamfetol as a new, differentiated potential treatment for the millions of patients living ADHD. With these results in the adult population in hand, we plan to initiate a trial in pediatric patients this year.”

Solriamfetol was safe and well tolerated in the trial, with a side effect profile that was consistent with the established safety profile of solriamfetol. Rates of adverse events were dose dependent. There were no serious adverse events reported in the trial.

About the FOCUS Trial

FOCUS (Forward Treatment of Attention Deficit and Hyperactivity Using Solriamfetol) was a Phase 3, randomized, double-blind, placebo-controlled, multicenter, 6-week, parallel group trial to evaluate the efficacy and safety of solriamfetol in adults with ADHD in the United States. A total of 516 adult patients with a primary diagnosis of ADHD were randomized 1:1:1 to treatment with solriamfetol 150 mg, solriamfetol 300 mg, or placebo, once daily for 6 weeks. The primary endpoint was the change from baseline in the Adult ADHD Investigator Symptom Rating Scale (AISRS) total score at Week 6. Total scores on the AISRS range from 0 to 54, with 0 corresponding to total absence of symptoms and higher scores corresponding to greater symptom severity. Mean baseline AISRS total scores for the solriamfetol 150 mg, solriamfetol 300 mg, and placebo groups were 39.1, 38.3, and 37.9 respectively. The key secondary endpoint was the change from baseline in the Clinical Global Impression of Severity (CGI-S) for ADHD at Week 6.

About Attention Deficit Hyperactivity Disorder

Attention deficit hyperactivity disorder (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 15.5 million adults and 7 million children in the U.S. are affected by ADHD,[4,5] with approximately two-thirds or more of children with ADHD continuing to experience symptoms into adulthood.[6] The total annual societal excess cost associated with adult ADHD in the U.S. has been estimated at over $120 billion.[7]

About Solriamfetol

Solriamfetol is a dopamine and norepinephrine reuptake inhibitor (DNRI), TAAR1 agonist, and 5-HT_{1A} agonist being developed for the treatment of attention deficit hyperactivity disorder (ADHD), major depressive disorder (MDD), binge eating disorder (BED), and excessive sleepiness associated with shift work disorder (SWD).

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.

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 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.

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References

1. American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders, 5 ed., Arlington, VA: American Psychiatric Publishing, 2013.
2. Brown TE. ADD/ADHD and Impaired Executive Function in Clinical Practice. Curr Psychiatry Rep. 2008 Oct;10(5):407-11.
3. Nestler E., Hyman S., and Malenka R. Molecular Neuropharmacology: A Foundation for Clinical Neuroscience, Second Edition, 2nd ed., New York: McGraw-Hill Professional, 2008.
4. Facts About ADHD in Adults. CDC. 2024.
5. Data and Statistics on ADHD. CDC. 2024.

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.
7. Schein J et al. Economic burden of attention-deficit/hyperactivity disorder among adults in the United States: a societal perspective. J Manag Care Spec Pharm. 2022 Feb;28(2):168-179.

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