Axsome Therapeutics Presents Data from Its Leading Neuroscience Pipeline at NEI Congress 2024

November 8, 2024

NEW YORK, Nov. 08, 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, today announced eight presentations spanning its innovative portfolio of late-stage products and product candidates in psychiatry and neurology at NEI Congress 2024, being held Nov. 7 - Nov. 10, 2024, in Colorado Springs, Colorado.

Details for the presentations are as follows:

Major Depressive Disorder

Title: AXS-05 (Auvelity®) in Major Depressive Disorder: Pooled Data from Two Six-Week Controlled Trials (GEMINI and ASCEND)
Presentation Date and Time: Friday, Nov. 8, 3:35 – 4:30 p.m. ET
Lead Author: Craig Chepke, MD, SUNY Upstate Medical University
Poster Number: 101

Title: Effects of AXS-05 (Auvelity®) in Improving Anhedonia and Interest-Activity Symptoms of MDD and the Associated Improvements in Functional Impairment
Presentation Date and Time: Friday, Nov. 8, 3:35 – 4:30 p.m. ET
Lead Author: Roger McIntyre, MD, Professor of Psychiatry and Pharmacology at the University of Toronto
Poster Number: 27

Title: Real-World Treatment Experiences and Expectations by Symptom Severity in Patients with Major Depressive Disorder
Presentation Date and Time: Friday, Nov. 8, 3:35 – 4:30 p.m. ET
Lead Author: Roger McIntyre, MD, Professor of Psychiatry and Pharmacology at the University of Toronto
Poster Number: 87

Title: Real-World AXS-05 (Auvelity®) Patient Characteristics in Major Depressive Disorder
Presentation Date and Time: Friday, Nov. 8, 3:35 – 4:30 p.m. ET
Lead Author: Andrew Muzyk, MD, Campbell University College of Pharmacy and Health Sciences, Buies Creek, NC
Poster Number: 116

Alzheimer's Disease Agitation

Title: Clinical Profile of AXS-05 in Treating Alzheimer's Disease-Related Agitation: Results from The Phase 2/3 Development Program
Presentation Date and Time: Friday, Nov. 8, 3:35 – 4:30 p.m. ET
Lead Author: Jeffrey Cummings, MD, ScD, Vice Chair of Research, UNLV Department of Brain Health
Poster Number: 25

OSA and Narcolepsy

Title: Solriamfetol for Excessive Daytime Sleepiness in Patients with Narcolepsy and OSA Reporting Anxiety and Depression in the Real-World SURWEY Study
Presentation Date and Time: Friday, Nov. 8, 3:35 – 4:30 p.m. ET
Lead Author: Ulf Kallweit, MD, Assistant Professor of Neurology at the University Witten/Herdecke, Germany
Poster Number: 98

Cognition

Title: Effects of Solriamfetol on Cognition in Obstructive Sleep Apnea with Excessive Daytime Sleepiness and Impaired Cognition in the SHARP Clinical Trial
Presentation Date and Time: Friday, Nov. 8, 3:35 – 4:30 p.m. ET
Lead Author: Yaroslav Winter, MD, Mainz Comprehensive Epilepsy and Sleep Medicine Center, department of neurology, Johannes Gutenberg-University, Mainz, Germany
Poster Number: 103

Title: Effects of Solriamfetol on Cognition in Patients with Excessive Daytime Sleepiness Associated with Narcolepsy in the Real-World SURWEY Study
Presentation Date and Time: Friday, Nov. 8, 3:35 – 4:30 p.m. ET
Lead Author: Yaroslav Winter, MD, Mainz Comprehensive Epilepsy and Sleep Medicine Center, department of neurology, Johannes Gutenberg-

University, Mainz, Germany
Poster Number: 97

About Axsome Therapeutics

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 www.axsome.com.

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 continued commercial success of the Company's Sunosi® and Auvelity® 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; 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 the Company's 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; 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 circumstance.

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