Axsome Therapeutics Acquires Subtype Selective GABA-A Receptor Positive Allosteric Modulator AZD7325 for the Treatment of Epilepsy

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Axsome obtains exclusive global rights to AZD7325, a novel oral selective $GABA_A$ α2,3 receptor positive allosteric modulator

Deepens Axsome's broad and innovative neuroscience portfolio with a synergistic early-stage program for epilepsy

NEW YORK, Nov. 06, 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 it has entered into an agreement to obtain exclusive global rights to AZD7325, a novel oral $GABA_A$ receptor α2,3 subtype-selective positive allosteric modulator (PAM), licensed from AstraZeneca AB (NASDAQ: AZN). AZD7325 has completed Phase 1 trials. Axsome intends to evaluate AZD7325 as a potential treatment for epilepsy and plans to begin Phase 2 trial-enabling activities in 2026.

"This transaction adds AZD7325, an earlier stage molecule with a differentiated mechanism of action, to our leading late-stage CNS portfolio," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. "We are excited to further deepen our research pipeline in a complementary way, and to extend our clinical efforts into epilepsy, an area where there is an urgent need for innovative new treatment options for patients."

AZD7325 has demonstrated anti-convulsant effects in preclinical seizure models. In clinical studies in over 700 patients to date, AZD7325 has demonstrated a favorable safety and tolerability profile.

Axsome will receive worldwide commercial, development, and manufacturing rights to AZD7325. The transaction was effectuated through Axsome's acquisition of a 100% equity interest in Baergic Bio, Inc., a subsidiary of Avenue Therapeutics, Inc. (OTC: ATXI), and concurrent amendment to the License Agreement between Baergic Bio and AstraZeneca. Under the terms of the Baergic Bio Share Purchase Agreement, Baergic Bio shareholders will receive a $0.3 million upfront payment and are eligible to receive development and regulatory milestone payments of $2.5 million for the first indication and $1.5 million for each indication thereafter, up to $79 million in potential sales-based milestones, and a tiered mid-to-high single-digit royalty on potential global net sales of AZD7325. Under the terms of the License Amendment, AstraZeneca will receive a cash upfront payment in the single digit millions and is eligible to receive development and regulatory milestone payments for each indication, sales-based milestones, and a tiered mid-to-high single-digit royalty on potential global net sales of AZD7325.

About Epilepsy

Epilepsy is a chronic and debilitating neurological disorder that affects approximately 3.4 million people in the U.S., with about 150,000 new cases diagnosed each year.[1-3] It is characterized by recurrent, unprovoked seizures, or sudden and uncontrolled surges of electrical activity in the brain that can cause involuntary movements, sensory disturbances, loss of awareness, or convulsions.[3,4] People living with epilepsy often face stigma, barriers to education and employment, higher rates of comorbid psychiatric conditions, and increased risk of premature mortality, contributing to reduced quality of life and social isolation.[5-7] Despite currently available treatment options, more than one-third of patients do not respond to treatment.[8]

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.

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