Axsome Therapeutics Acquires Selective PDE10A Inhibitor Balipodect for the Treatment of Schizophrenia and Other Neuropsychiatric Conditions

April 1, 2026

Axsome obtains exclusive global rights to balipodect, a potentially first-in-class selective phosphodiesterase 10A inhibitor

Acquisition further expands Axsome's industry-leading CNS portfolio with a novel mechanism for neuropsychiatric conditions

NEW YORK, April 01, 2026 (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 asset purchase agreement to obtain exclusive global rights to TAK-063 (balipodect), a novel, oral, potent, and selective phosphodiesterase 10A (PDE10A) inhibitor from Takeda. Axsome intends to develop the selective inhibitor for the treatment of schizophrenia and Tourette syndrome, and plans to begin Phase 3 trial-enabling activities for the schizophrenia indication in 2026.

"We are pleased to add balipodect, a selective PDE10A inhibitor, to our industry-leading neuroscience pipeline. We believe that its new and potentially first-in-class mechanism of action is relevant to multiple neuropsychiatric conditions, and we are well positioned to advance its development initially in schizophrenia and Tourette syndrome," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. "This novel molecule complements and enhances our innovative pipeline as we continue to develop and deliver differentiated treatment options to improve the brain health of millions of individuals."

Balipodect has completed a 164-patient proof-of-concept Phase 2 trial in schizophrenia. The selective PDE10A inhibitor has demonstrated a favorable safety and tolerability profile in clinical studies in over 360 individuals to date.

Under the terms of the agreement, Axsome obtained worldwide commercial, development, and manufacturing rights to balipodect. Takeda received an upfront payment and is eligible to receive additional payments related to development, regulatory, and commercial milestones for the first two indications, as well as royalties related to potential global net sales.

About Schizophrenia

Schizophrenia is a debilitating chronic neuropsychiatric condition characterized by three main symptom domains, including positive (e.g., hallucinations, delusions, disorganized thinking and speech), negative (e.g., loss of motivation, social withdrawal, diminished emotional expression, decreased ability to feel pleasure), and cognitive (e.g., impaired attention and concentration, memory deficits).[1,2] It is part of a broader spectrum of related psychotic disorders that impact approximately 3.7 million people in the United States, and is one of the leading causes of disability worldwide.[3,4] Schizophrenia is associated with significantly impaired daily functioning, markedly reduced life expectancy, and substantial social and economic burden.[5,6]

About Balipodect

Balipodect is a potent selective inhibitor of phosphodiesterase 10A (PDE10A), an enzyme selectively expressed in medium spiny neurons of the striatum.[7] Inhibition of PDE10A is a new mechanism of action and potential therapeutic target for several neuropsychiatric conditions including schizophrenia and Tourette syndrome. The selective inhibitor regulates levels of cAMP and cGMP downstream of dopamine D_1 and D_2 receptor signaling in the medium spiny neurons of the striatum. In preclinical and clinical studies to date, balipodect did not increase glucose or prolactin levels, and this lack of metabolic effects may be due in part to the selective, striatal expression of PDE10A and the activity of balipodect downstream of the dopamine receptor in D_1- and D_2-receptor-expressing neurons.[7-10]

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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Source: Axsome Therapeutics, Inc.