Axsome Therapeutics Enters into License Agreement with Pharmanovia to Expand Commercialization and Further Develop Sunosi® (solriamfetol) in Europe

February 22, 2023

Axsome to receive an upfront payment of $66 million, and is eligible to receive sales-based and other milestones totaling up to $101 million

Pharmanovia is responsible for all ongoing and future clinical studies in Europe and MENA

NEW YORK, Feb. 22, 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 entered into an exclusive license agreement with Pharmanovia to commercialize and further develop Sunosi® (solriamfetol), the first and only dual-acting dopamine and norepinephrine reuptake inhibitor shown to improve wakefulness in adults living with excessive daytime sleepiness (EDS) due to narcolepsy or obstructive sleep apnea (OSA), in Europe and certain countries in the Middle East and North Africa (MENA).

Under the terms of the agreement, Pharmanovia will be responsible for marketing Sunosi in Europe and MENA regions and will assume responsibility for all local clinical and regulatory activities and requirements including studies in pediatric patients. Axsome will receive an upfront payment of $66 million and is eligible to receive sales-based and other milestones totaling up to $101 million. Axsome will receive a royalty percentage in the mid-twenties on net sales.

"We are pleased to collaborate with Pharmanovia, a company which shares our excitement and commitment to maximize the potential of Sunosi for patients worldwide," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. "Pharmanovia's strong commercial platform is well suited to expand the availability of and access for this important treatment across Europe and MENA."

James Burt, Chief Executive Officer of Pharmanovia said, "We are proud to be able to deliver Sunosi, a novel, first-in-class neurological medicine, to the millions of patients suffering from EDS due to narcolepsy or OSA in Europe and soon in MENA. We are delighted to partner with Axsome, a leading CNS-focused biopharmaceutical company, and to expand the overseas launch and further the clinical development of Sunosi. A pivotal Phase 3 study and longer-term extension study, exploring the safety and effectiveness of Sunosi in children with narcolepsy, will be initiated by Pharmanovia, with the aim of bringing this breakthrough therapy to young people affected by this debilitating disease."

Sunosi was approved by the European Medicines Agency (EMA) in 2020 based on data from randomized placebo-controlled studies in patients with EDS associated with narcolepsy or OSA that demonstrated the superiority of Sunosi relative to placebo.

Morgan Stanley & Co. LLC is acting as the exclusive financial advisor to Axsome. DLA Piper US LLP is acting as legal advisor to Axsome.

* *USD/Euro conversion based on exchange rate as of Feb. 20, 2023*

About Sunosi® (solriamfetol)

Sunosi is a dual-acting dopamine and norepinephrine reuptake inhibitor shown to improve wakefulness in adults living with excessive daytime sleepiness (EDS) due to narcolepsy or obstructive sleep apnea (OSA). Sunosi received U.S. Food and Drug Administration approval on March 20, 2019 to improve wakefulness in adult patients with EDS associated with narcolepsy or OSA and was designated a Schedule IV medicine by the U.S. Drug Enforcement Agency on June 17, 2019. SK Biopharmaceuticals Co., Ltd., the discoverer of the compound, maintains rights in 12 Asian markets, including Korea, China and Japan. Sunosi has orphan drug designation for narcolepsy in the United States.

About Obstructive Sleep Apnea and Excessive Daytime Sleepiness

Obstructive sleep apnea, commonly referred to as sleep apnea, is a highly prevalent disease (as high as 14% in men and 5% in women) in which excessive daytime sleepiness is a major presenting complaint in many cases. Positive Airway Pressure (PAP) therapy, with its most common form being Continuous Positive Airway Pressure (CPAP), has been shown to be an effective therapy for sleep apnea that frequently results in improvement in excessive daytime sleepiness in many patients; however, not all patients tolerate CPAP therapy and among those who tolerate CPAP, usage is highly variable. Excessive daytime sleepiness may persist in people with sleep apnea despite using CPAP.

About Narcolepsy

Narcolepsy is a serious and debilitating neurological condition that causes dysregulation of the sleep-wake cycle and is characterized clinically by excessive daytime sleepiness, cataplexy, hypnagogic hallucinations, sleep paralysis, and disrupted nocturnal sleep. Narcolepsy afflicts an estimated 185,000 individuals in the U.S. Narcolepsy interferes with cognitive, psychological, and social functioning, increases the risk of work- and driving-related accidents, and is associated with a 1.5-fold higher mortality rate.

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.

About Pharmanovia

Pharmanovia is a global lifecycle management healthcare company. Our purpose is to make medicines fit for tomorrow, to improve the lives of patients globally. We do this by rediscovering, repurposing or re-engineering established medicines to improve patient outcomes and experiences. With a diverse and growing team in over 140 countries across the globe, we deliver high-quality solutions, ethically and sustainably, across our four core therapeutic areas – Oncology, Endocrinology, Neurology and Cardiovascular.

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 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, 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.

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