

Axsome Therapeutics Voices its Commitment to Mental Health on World Mental Health Day 2022

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NEW YORK, Oct. 10, 2022 (GLOBE NEWSWIRE) -- Axsome Therapeutics, Inc. (NASDAQ: AXSM), a biopharmaceutical company developing and delivering novel therapies for the management of central nervous system (CNS) disorders, is joining the World Health Organization's (WHO) 2022 World Mental Health Day campaign to make mental health and well-being for all a global priority.

According to the WHO's World Mental Health Report, approximately one billion people are living with a mental disorder and nearly three hundred million adults have depression worldwide [1,2]. The ubiquity of mental health disorders results in an estimated 12 billion workdays lost annually due to depression and anxiety alone, and results in costs to the global economy of nearly one trillion dollars [3].

"Axsome shares the World Health Organization's vision of a world in which mental health is valued, promoted and protected. We are pleased to add our voice to raise awareness of mental health on this important day," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. "Given the growing prevalence of depression and other mental health conditions, the need for effective new treatments that are accessible to all has never been greater. We are committed to doing our part to discover, develop and deliver new medicines to the millions of individuals living with mental health conditions in the U.S. and around the globe."

A variety of mental well-being resources from the World Health Organization are available at <u>https://www.who.int/news-room/feature-stories/mental-well-being-resources-for-the-public</u>.

As part of Axsome's commitment to depression education, resources and tools are available at <u>www.talkdepressettling.com</u> to help support those affected by depression.

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 <u>axsome.com</u>. The Company may occasionally disseminate material, nonpublic information on the company website.

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® product and the success of our efforts to obtain any additional indication(s) with respect to Sunosi; the commercial success of our AuvelityTM product and the success of our efforts to obtain any additional indication(s) with respect to 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 (including, but not limited to,; 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 product candidates, if approved; the Company's anticipated capital requirements, including the amount of capital required for the successful 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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References

- 1. World mental health report: transforming mental health for all. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.
- 2. World Health Organization. (2021, September 13). Depression. World Health Organization Fact Sheets. <u>https://www.who.int</u> /news-room/fact-sheets/detail/depression
- 3. World Health Organization. (2022, September 28). Joint News Release. <u>https://www.who.int/news/item/28-09-2022-</u> who-and-ilo-call-for-new-measures-to-tackle-mental-health-issues-at-work



Source: Axsome Therapeutics, Inc.