Axsome Therapeutics Announces Results of the SUPPORT Survey of Patients with Major Depressive Disorder Presented at the American Society of Clinical Psychopharmacology Association (ASCP) 2022 Annual Meeting

June 6, 2022

Survey conducted in collaboration with the Depression and Bipolar Support Alliance (DBSA)

Survey respondents reported persistence of high levels of depressive symptoms and interference with work and daily functioning despite treatment

Respondents reported low levels of hope and high levels of dissatisfaction with current treatments

NEW YORK, June 06, 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, today announced the results of the SUPPORT (Studying the Impact of Patient Treatment Experiences on Patient Hope for Future Major Depressive Disorder Pharmacotherapies) survey of 385 patients with depression, demonstrating persistence of high levels of depressive symptoms despite treatment, substantial interference with work and daily life, low levels of patient hope, and high levels of patient dissatisfaction with current treatments.

The SUPPORT survey assessed treatment experiences and expectations in patients taking antidepressants for major depressive disorder (MDD). The web-based survey was developed in collaboration with the Depression and Bipolar Support Alliance (DBSA) and the DBSA Peer Council; Roger McIntyre, MD, Professor of Psychiatry and Pharmacology, University of Toronto, Canada and Chair of the DBSA Scientific Advisory Board; and Greg Mattingly, MD, Associate Clinical Professor of Psychiatry at Washington University and President of the Midwest Research Group. The SUPPORT results were presented on June 1, 2022 at the American Society of Clinical Psychopharmacology (ASCP) 2022 Annual Meeting, held in Scottsdale, Arizona and virtually.

“Millions of people in the United States are currently living with depression. There is a critical and urgent need for new and effective treatments, as evidenced by the findings from the SUPPORT survey, for patients experiencing depression,” said Michael Pollock, Chief Executive Officer of the Depression and Bipolar Support Alliance. “The Depression and Bipolar Support Alliance (DBSA) envisions wellness for people living with mood disorders and it is our mission to provide hope, help, support, and education to improve the lives of people who have mood disorders. We are pleased to partner with Axsome to increase support for and empower those experiencing depression.”

Patients surveyed continued to experience substantial levels of depression despite being on a current antidepressant, and reported high levels of dissatisfaction with currently available treatments. Despite 85% of survey participants being currently on an antidepressant, 68% were still experiencing moderate, severe, or very severe depressive symptoms. Nearly three quarters (74%) of respondents reported they were not completely satisfied with how their current MDD treatment relieves their symptoms of depression. Nearly half (48%) reported that at least one of the side effects with their current treatment was at least somewhat bothersome. Of the survey population, 82% agreed that people with depression deserve to receive better medications than what is currently available.

Patients surveyed reported substantial interference with work and daily life productivity, and exhibited low levels of hope about current and future treatments for depression. Overall, 52% reported having difficulty with work or daily life productivity as a result of depression. More than half (54%) of surveyed patients do not believe that it is possible for their depression to be in remission.

“Depression is a serious and debilitating condition that is increasing in prevalence. The results of this large survey indicate that severe symptoms persist in the majority of patients even with current treatment, and substantially impact their ability to work and perform daily tasks,” said Dr. Roger McIntyre, Professor of Psychiatry and Pharmacology at the University of Toronto. “These findings reinforce the substantial unmet need for new treatment options for patients living with this potentially life-threatening condition.”

People living with depression and their loved ones can access additional information about the survey, learn more about the condition, and find links to additional support by visiting www.talkdepressettling.com.

About the SUPPORT Survey

The SUPPORT (Studying the Impact of Patient Treatment Experiences on Patient Hope for Future Major Depressive Disorder Pharmacotherapies) survey was developed in conjunction with the Depression and Bipolar Support Alliance (DBSA), and the DBSA Peer Council; Roger McIntyre, MD, Professor of Psychiatry and Pharmacology, University of Toronto, Canada and Chair of the DBSA Scientific Advisory Board; and Greg Mattingly, MD, Associate Clinical Professor of Psychiatry at Washington University and President of the Midwest Research Group. The respondents were recruited from a large global patient research panel and in conjunction with DBSA. A total of 385 U.S. adults with self-reported diagnoses of MDD completed the survey. The survey was conducted online in December 2021 and January 2022.

About Major Depressive Disorder

Major depressive disorder (MDD) is a debilitating, chronic, biologically-based disorder characterized by low mood, inability to feel pleasure, feelings of guilt and worthlessness, low energy, and other emotional and physical symptoms, and which impairs social, occupational, educational, or other important functioning. In severe cases, MDD can result in suicide. According to the National Institutes of Health, an estimated 7% of U.S. adults, or approximately 19 million, experience MDD each year[1]. According to the World Health Organization (WHO), depression is the leading cause of disability worldwide, and is a major contributor to the overall global burden of disease[2]. Nearly two-thirds of diagnosed and treated patients do not experience adequate treatment response with currently available first-line therapy[3], highlighting the need for additional therapies with new mechanisms of action.

About Depression and Bipolar Support Alliance (DBSA)

The Depression and Bipolar Support Alliance (DBSA) is a leading national organization focusing on mood including depression and bipolar disorder, which affect over 21 million Americans, account for over 50% of the nation's suicides every year, and cost $23 billion in lost workdays and other workplace losses. DBSA offers peer-based, wellness-oriented support and empowering services and resources available when people need them, where they need them, and how they need to receive them—online 24/7, in local support groups, in audio and video casts, or in printed materials distributed by DBSA, their chapters, and in mental health care facilities across America. Through their extensive online and print resources and nearly 600 support groups and more than 200 chapters, DBSA reaches millions of people each year with in-person and online peer support; current, readily understandable information about depression and bipolar disorder; and empowering tools focused on an integrated approach to wellness.

About Axsome Therapeutics, Inc.

Axsome Therapeutics, Inc. is a biopharmaceutical company developing and delivering novel therapies for 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.

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 newly acquired Sunosi product; 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 potential filing issues or issues identified by FDA during the substantive review may impact the potential approvability of the Company's NDA submission for AXS-05 in MDD or the timing of such approval; 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 potential for the ASCEND clinical trial, combined with the GEMINI clinical trial results, to provide a basis for approval of AXS-05 for the treatment of major depressive disorder and accelerate its development timeline and commercial path to patients; 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 continued commercialization of Sunosi and for the Company's commercial launch of its 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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Source: Axsome Therapeutics, Inc.