Axsome Therapeutics to Present Five Abstracts Including New Data from the Positive SHARP Study of SUNOSI® (solriamfetol) in Participants with Cognitive Impairment with Excessive Daytime Sleepiness in Obstructive Sleep Apnea at the 2023 American Academy of Neurology (AAN) Annual Meeting

April 21, 2023

NEW YORK, April 21, 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 will be presenting five abstracts at the upcoming 2023 American Academy of Neurology (AAN) Annual Meeting, being held from April 22-27 in Boston. These presentations include new data from the SHARP study, a randomized, double-blind, placebo-controlled, crossover, multicenter trial in 59 patients with excessive daytime sleepiness (EDS) associated with obstructive sleep apnea (OSA) and impaired cognitive function, from which positive topline results were announced in October 2022[1].

New data from the SHARP (Solriamfetol's Effect on Cognitive Health in Apnea Participants During a Randomized Placebo-controlled) study being presented at AAN include detailed secondary endpoints for the British Columbia Cognitive Complaints Inventory (BC-CCI) and the Epworth Sleepiness Scale (ESS).

"The SHARP study is exciting because it overcomes treatment barriers associated with the complex relationship between cognitive impairment and OSA," said Hans Van Dongen, Ph.D., Professor at Washington State University and first author of the SHARP study abstract. "Endpoints from the SHARP study show potential clinical benefit for patients taking solriamfetol versus placebo, suggesting it can be a robust option for the treatment of patients with EDS due to OSA. These new data, and other studies being shared at AAN, support the notion that solriamfetol performs according to label specifications and has potential to make a meaningful difference for patients with OSA and excessive daytime sleepiness."

Additional presentations at the AAN conference highlight data on the TAAR1 agonist mechanism of action of solriamfetol, data from the ongoing SURWEY real-world experience study of Sunosi, as well as data on AXS-07, Axsome's novel, oral, rapidly absorbed, multi-mechanistic, investigational medicine for the acute treatment of migraine.

Details for the upcoming AAN presentations are as follows:

Title: Effects of Solriamfetol on Cognitive Function in Participants with Cognitive Impairment Associated with Excessive Daytime Sleepiness in Obstructive Sleep Apnea: Results of the SHARP Study
Poster Session: P4 - Poster Session 4
Presenting Author: Eileen Leary, Ph.D., Senior Director of Clinical Development at Axsome
Date/Time: Monday, April 24, 2023, from 8 a.m. – 9 a.m. ET

Title: Preclinical Pharmacology of Solriamfetol: Potential Mechanisms for Wake Promotion
Poster Session: P4 - Poster Session 4
Presenting Author: Gregory S. Parks, Ph.D., Executive Director of Medical Affairs at Axsome
Date/Time: Monday, April 24, 2023, from 8 a.m. – 9 a.m. ET

Title: Solriamfetol Real World Experience Study: Initiation, Titration, Safety, Effectiveness, and Experience During Follow-Up for Patients with Narcolepsy from Germany
Poster Session: P4 - Poster Session 4
Presenting Author: Samantha Floam, DMD, Director of Medical Affairs at Axsome
Date/Time: Monday, April 24, 2023, from 8 a.m. – 9 a.m. ET

Title: Identifying Areas of Unmet Need Among People with Migraine with an Inadequate Response to Prior Acute Therapies: Results from the MOMENTUM trial
Poster Session: P7 - Poster Session 7
Presenting Author: Zachariah Thomas, PharmD, MPH, Executive Director of Medical Affairs at Axsome
Date/Time: Monday, April 24, 2023, from 8 a.m. – 9 a.m. ET

Title: Efficacy of AXS-07 (MOSEIC™ Meloxicam and Rizatriptan) in Patients with Risk Factors for Inadequate Response to Acute Migraine Medications
Poster Session: P13 - Poster Session 13
Presenting Author: Stuart J. Tepper, MD, Professor of Neurology, Geisel School of Medicine at Dartmouth
Date/Time: Thursday, April 27, 2023, from 8 a.m. – 9 a.m. ET

About the SHARP Trial

SHARP (Solriamfetol's Effect on Cognitive Health in Apnea Participants During a Randomized Placebo-controlled Study) was a randomized, double-blind, placebo-controlled, crossover, multicenter, trial in which 59 patients with EDS and OSA, who were experiencing cognitive impairment, were all treated with Sunosi (solriamfetol) for 2 weeks, and with placebo for 2 weeks, with the treatment periods separated by a 1 week washout. Patients were randomized in a 1:1 ratio either to treatment with Sunosi followed by placebo (sequence 1), or to treatment with placebo followed by Sunosi (sequence 2). Sunosi was administered orally once daily, starting at 75 mg per day for the first three days and 150 mg per day for the remainder of the 2-week treatment period. The primary outcome measure was the Digit Symbol Substitution Test subtest of the Repeatable Battery for the Assessment of Neuropsychological Status (DSST RBANS). The Digit Symbol Substitution subtest is also referred to as "Coding." The prespecified primary endpoint was the change from baseline in cognitive function as measured by the DSST RBANS after 2 weeks of treatment (average of the 2-, 4-, 6-, and 8-hour post-dose DSST RBANS scores). Secondary endpoints included patient reported measures of cognition including the British Columbia Cognitive Complaints Inventory (BC-CCI) and the Patient Global Impression of Severity (PGI-S) for cognitive symptoms; and the Epworth Sleepiness Scale (ESS) to measure wakefulness. The secondary endpoints were analyzed in a pre-specified testing sequence. All analyses were conducted on an intent-to-treat basis.

About the SUnosi Real World Experience studY (SURWEY) Study

SURWEY is an ongoing retrospective chart review among physicians in Germany, prescribing solriamfetol for patients with EDS associated with narcolepsy or OSA. Physicians prescribing solriamfetol to ≥10 patients with EDS associated with narcolepsy can take part and provide data from the patients' medical records. Eligible patients are ≥18 years old, have been diagnosed with EDS associated with narcolepsy, achieve a stable dose on solriamfetol, and complete ≥6 weeks of solriamfetol treatment. Data related to solriamfetol dosing/titration, changes in Epworth Sleepiness Scale (ESS) scores, physician and patient impression of effectiveness, and adverse events are recorded and summarized descriptively. The present analysis focuses on data from patients with narcolepsy from Germany.

About Sunosi® (solriamfetol)

Sunosi is a dual-acting dopamine and norepinephrine reuptake inhibitor indicated to improve wakefulness in adult patients with excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA). Sunosi does not treat the underlying cause of OSA and Sunosi does not take the place of any device prescribed for OSA, such as a continuous positive airway pressure (CPAP) machine. It is important that you continue to use these treatments as prescribed by your healthcare provider. 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. Sunosi is protected by a robust patent estate with expiries out to 2040.

More information about Sunosi, including Full Prescribing Information and Medication Guide, is available here.

Important Safety Information

Before taking SUNOSI, tell your doctor about all of your medical conditions, including if you:

- have heart problems, high blood pressure, kidney problems, diabetes, or high cholesterol.
- have had a heart attack or a stroke.
- have a history of mental health problems (including psychosis and bipolar disorders), or of drug or alcohol abuse or addiction.
- are pregnant or planning to become pregnant. It is not known if SUNOSI will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if SUNOSI passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take SUNOSI.

Do not take SUNOSI if you are taking, or have stopped taking within the past 14 days, a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI).

What are the possible side effects of SUNOSI?

SUNOSI may cause serious side effects, including:

- **Increased blood pressure and heart rate**. SUNOSI can cause blood pressure and heart rate increases that can increase the risk of heart attack, stroke, heart failure, and death. Your doctor should check your blood pressure before, and during, treatment with SUNOSI. Your doctor may decrease your dose or tell you to stop taking SUNOSI if you develop high blood pressure that does not go away during treatment with SUNOSI.
- **Mental (psychiatric) symptoms including anxiety, problems sleeping (insomnia), irritability, and agitation.** Tell your doctor if you develop any of these symptoms. Your doctor may change your dose or tell you to stop taking SUNOSI if you develop side effects during treatment with SUNOSI.

The most common side effects of SUNOSI include:

- headache
- decreased appetite
- problems sleeping
- nausea
- anxiety

These are not all the possible side effects of SUNOSI. Call your doctor for advice about side effects.

SUNOSI (solriamfetol) is available in 75 mg and 150 mg tablets and is a federally controlled substance (CIV) because it contains solriamfetol that can be a target for people who abuse prescription medicines or street drugs. Keep SUNOSI in a safe place to protect it from theft. Never give or sell your SUNOSI to anyone else because it may cause death or harm them and it is against the law. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please find full Prescribing Information here: https://sunosihcp.com/assets/files/sunosi-pi.pdf

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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 AXS-07

AXS-07 is a novel, oral, rapidly absorbed, multi-mechanistic investigational medicine for the acute treatment of migraine, consisting of MoSEIC™ meloxicam and rizatriptan. Meloxicam is a new molecular entity for migraine enabled by Axsome's MoSEIC™ (Molecular Solubility Enhanced Inclusion Complex) technology, which results in rapid absorption of meloxicam while maintaining a long plasma half-life. Meloxicam is a COX-2 preferential non-steroidal anti-inflammatory drug and rizatriptan is a 5-HT1B/1D agonist. AXS-07 is designed to provide rapid, enhances and consistent relief of migraine, with reduced symptom recurrence. AXS-07 is protected by a robust patent estate extending out to at least 2036. AXS-07 is not approved by the FDA.

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.

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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References:

1. Axsome Therapeutics SHARP Study Topline Data Press Release, October 3, 2023: https://axsometherapeuticsinc.gcs-web.com/news-releases/news-release-details/axsome-therapeutics-announces-sunosir-solriamfetol-meets-primary

Source: Axsome Therapeutics, Inc.