Axsome Therapeutics to Present Data and Post-Hoc Analyses on Auvelity® and Sunosi® at the 2023 American Society of Clinical Psychopharmacology (ASCP) Annual Meeting

May 30, 2023

Data on Auvelity demonstrating improved functioning in major depressive disorder

Data on Sunosi demonstrating improved cognitive function in patients with excessive daytime sleepiness associated with obstructive sleep apnea

NEW YORK, May 30, 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 presentations on Auvelity® (dextromethorphan-bupropion), Sunosi® (solriamfetol), and disease state at the upcoming American Society of Clinical Psychopharmacology (ASCP) Annual Meeting, being held from May 30-June 3 in Miami. The presentations on Auvelity incorporate new data and post-hoc analyses including demonstration of functional improvement in patients with major depressive disorder (MDD). The presentations on Sunosi include data from the SHARP (Solriamfetol's Effect on Cognitive Health in Apnea Participants During a Randomized Placebo-controlled) study demonstrating improvement in cognitive function in patients with excessive daytime sleepiness (EDS) associated with obstructive sleep apnea (OSA).

"MDD is the leading cause of disability worldwide and improvement in functioning is critically important to people with MDD. Workplace costs, which are driven by presenteeism, are the major driver of the total economic burden of MDD, which exceeds $326 billion in the United States[1]," said Andrew Cutler, MD, Associate Clinical Professor of Psychiatry, SUNY Upstate Medical University and Chief Medical Officer, Neuroscience Education Institute. "These data add to the existing clinical evidence for Auvelity in improving patient-centered outcomes in MDD and demonstrate the potential for Auvelity to improve functional impairment in MDD and to reduce key drivers of MDD-related costs."

Details for the upcoming ASCP presentations are as follows:

Title: AXS-05 (Dextromethorphan-Bupropion) Significantly Improved Functioning in Major Depressive Disorder: Analysis of the Domains of the Sheehan Disability Scale
Oral Session: Poinciana 1 2
Lead Author: Andrew Cutler, MD, SUNY Upstate Medical University and Neuroscience Education Institute
Date/Time: Tuesday, May 30, 2023, from 4:15 p.m. – 4:30 p.m. ET

Title: Impact of AXS-05 (Dextromethorphan-Bupropion) on Patient-Reported Insomnia Symptoms: Results from the GEMINI Trial
Poster Session: Salon 4
Lead Author: Zachariah Thomas, PharmD, MPH, Axsome Therapeutics
Date/Time: Wednesday, Wednesday, May 31, 2023, from 11:15 a.m. – 1 p.m. ET

Title: Assessment of Withdrawal Symptoms After Discontinuation of AXS-05 (Dextromethorphan-Bupropion) Treatment: Results from the GEMINI Trial
Poster Session: Salon 4
Lead Author: Rakesh Jain, MD Texas Tech University School of Medicine-Permian Basin
Date/Time: Thursday, June 1, 2023, from 12:30 p.m. – 2:15 p.m. ET

Title: Major Depressive Disorder Disease and Patient Characteristics Associated with Inadequate Treatment Experience: Results from the SUPPORT Study
Poster Session: Salon 4
Lead Author: Gregory Mattingly, MD, Associate Clinical Professor of Psychiatry at Washington University and President of the Midwest Research Group
Date/Time: Thursday, June 1, 2023, from 12:30 p.m. – 2:15 p.m. ET

Title: Excessive Daytime Sleepiness in a Real-World Study of Participants with Obstructive Sleep Apnea with or without Comorbid Depression
Poster Session: Salon 4
Lead Author: Samantha Floam, DMD, Axsome Therapeutics
Date/Time: Thursday, June 1, 2023, from 12:30 p.m. – 2:15 p.m. ET

Title: Preclinical Pharmacology of Solriamfetol: Potential Mechanisms for Wake Promotion
Poster Session: Salon 4
Lead Author: Gregory Parks, PhD, Axsome Therapeutics
Date/Time: Thursday, June 1, 2023, from 12:30 p.m. – 2:15 p.m. ET

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: Salon 4
Lead Author: Eileen Leary, PhD, Axsome Therapeutics
Date/Time: Wednesday, May 31, 2023, from 11:15 a.m. – 1 p.m. ET

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 8.3% of U.S. adults, or approximately 21 million, experience MDD each year[2]. 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[3]. Nearly two-thirds of diagnosed and treated patients do not experience adequate treatment response with currently available first-line therapy[4], highlighting the need for additional therapies with new mechanisms of action.

About AUVELITY®
AUVELITY is a novel, oral, NMDA receptor antagonist with multimodal activity approved for the treatment of MDD in adults. AUVELITY is a proprietary extended-release oral tablet containing dextromethorphan HBr (45 mg) and bupropion HCl (105 mg). The dextromethorphan component of AUVELITY is an antagonist of the NMDA receptor (an ionotropic glutamate receptor) and a sigma-1 receptor agonist. These actions are thought to modulate glutamatergic neurotransmission. The bupropion component of AUVELITY is an aminoketone and CYP2D6 inhibitor which serves to increase and prolong the blood levels of dextromethorphan. The exact mechanism of action of Auvelity in the treatment of depression is unclear. AUVELITY received Breakthrough Therapy designation from the FDA for the treatment of MDD.

INDICATION AND IMPORTANT SAFETY INFORMATION

WHAT IS AUVELITY (aw-VEHL-ah-tee)? It is a prescription oral medicine used to treat adults with major depressive disorder (MDD). It is not known if Auvelity is safe and effective for use in children.
Auvelity is not approved for uses other than the treatment of MDD. The ingredients in Auvelity, bupropion and dextromethorphan, are the same ingredients found in some other medicines approved for other uses.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT AUVELITY?
Auvelity and other antidepressant medicines may increase suicidal thoughts and actions in some children, adolescents, and young adults, especially within the first few months of treatment or when the dose is changed. Auvelity is not for use in children.
You should pay close attention to any new or sudden changes in mood, behavior, thoughts, or feelings or if you develop suicidal thoughts or actions. This is very important when starting or changing the dose of an antidepressant medicine.
Call your healthcare provider (HCP) or get emergency help right away if you or your loved one have any of the following symptoms, especially if they are new, worse, or worry you:

- suicidal thoughts or actions
- new or worsening depression or anxiety
- agitation or restlessness
- trouble sleeping (insomnia)
- acting aggressive, being angry violent
- an extreme increase in activity and talking (mania)
- panic attacks
- new or worsening irritability
- acting on dangerous impulses
- other unusual changes in behavior or mood

Do not take Auvelity if you:

- have or had a seizure disorder.
- have or had an eating disorder like anorexia or bulimia.
- have recently and suddenly stopped drinking alcohol or use medicines called benzodiazepines, barbiturates, or anti-seizure medicines, and you have recently suddenly stopped taking them.
- are taking a monoamine oxidase inhibitor (MAOI), have stopped taking an MAOI in the last 14 days, or are being treated with the antibiotic linezolid or intravenous methylene blue. Ask your HCP or pharmacist if you are unsure whether you take an MAOI. Do not start taking an MAOI until you have stopped taking Auvelity for at least 14 days.
- are allergic to dextromethorphan, bupropion, or any other ingredients in Auvelity.

Auvelity may cause serious side effects. Ask your HCP how to recognize the serious side effects below and what to do if you think you have one:
Seizures. There is a risk of seizures during treatment with Auvelity. The risk is higher if you take higher doses of Auvelity, have certain medical problems, or take Auvelity with certain other medicines. Do not take Auvelity with other medicines unless your healthcare provider tells you to.
If you have a seizure during treatment with Auvelity, stop taking Auvelity and call your HCP right away. Do not take Auvelity again if you have a seizure.
Increases in blood pressure (hypertension). Some people may get high blood pressure during treatment with Auvelity. Your HCP should check your blood pressure before you start taking and during treatment with Auvelity.
Manic episodes. Manic episodes may happen in people with bipolar disorder who take Auvelity. Symptoms may include:

- greatly increased energy

- racing thoughts
- unusually grand ideas
- talking more or faster than usual
- severe trouble sleeping
- reckless behavior
- excessive happiness or irritability

Unusual thoughts or behaviors. One of the ingredients in Auvelity (bupropion) can cause unusual thoughts or behaviors, including delusions (believing you are someone else), hallucinations (seeing or hearing things that are not there), paranoia (feeling that people are against you), or feeling confused. If this happens to you, call your HCP.
Eye problems (angle-closure glaucoma). Auvelity may cause a type of eye problem called angle-closure glaucoma in people with certain other eye conditions. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are. Call your HCP if you have eye pain, changes in your vision, or swelling or redness in or around the eye.
Dizziness. Auvelity may cause dizziness which may increase your risk for falls.
Serotonin syndrome. A potentially life-threatening problem called serotonin syndrome can happen when you take Auvelity with certain other medicines. Call your HCP or go to the nearest hospital emergency room right away if you have any of the following signs and symptoms:

- agitation
- hallucinations
- confusion
- coma
- fast heartbeat
- blood pressure changes
- dizziness
- sweating
- flushing
- high body temperature (hyperthermia)
- shaking (tremors), stiff muscles, or muscle twitching
- loss of coordination
- seizures
- nausea, vomiting, diarrhea

COMMON SIDE EFFECTS

The most common side effects of Auvelity include dizziness, headache, diarrhea, feeling sleepy, dry mouth, sexual function problems, and excessive sweating.
These are not all the possible side effects of Auvelity. Tell your doctor if you have any side effects. You can report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch.

BEFORE USING

- Tell your HCP about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
- It is important to tell your HCP if you are taking:
    - other medicines containing bupropion or dextromethorphan
    - medicines to treat depression, anxiety, psychotic or thought disorders, including selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants
    - theophylline
    - corticosteroids
    - oral diabetes medicines or use insulin to control your blood sugar
    - medicines to control appetite (anorectic)
    - nicotine medicines to help you stop smoking
    - street (illicit) drugs
    - benzodiazepines, sedative-hypnotic (sleep medicines), or opiates
- If you are unsure if you take any of these medicines, ask your HCP. They can tell you if it is safe to take Auvelity with your other medicines.
- Tell your HCP if you are pregnant or plan to become pregnant. Auvelity may harm your unborn baby if you take it during pregnancy. Auvelity is not recommended during pregnancy. Your HCP will prescribe another treatment for females who plan to become pregnant.
- One of the ingredients in Auvelity passes into your breast milk. Do not breastfeed during treatment with Auvelity and for 5 days after the final dose.

Tell your HCP about all your medical conditions, including if you:

- have problems with your liver or kidneys.
- have diabetes, heart disease, or high blood pressure.
- have a history of seizure, stroke, eating disorder, head injury, or have a tumor in your brain or spinal cord.
- have a history of alcohol or drug abuse.
- have a history of seizure, eating disorder, or abuse alcohol or drugs.
- have low blood sugar, low blood sodium levels, or a history of falls.
- you take certain other medicines that could interact with Auvelity.
- have or had a condition known as bipolar disorder, a family history of bipolar disorder, suicide, or depression.
- have high pressure in the eye (glaucoma).

Review the list below with your HCP. Auvelity may not be right for you if:

- you drink a lot of alcohol.
- you abuse prescription or street drugs.
- you are pregnant or plan to become pregnant.
- you are breastfeeding or plan to breastfeed.

HOW TO TAKE

- Auvelity is available by prescription only.
- Take Auvelity exactly as instructed by your HCP.
- Take Auvelity 1 time a day for 3 days, then increase your dose to 2 times a day (taken at least 8 hours apart). Do not take more than 2 Auvelity tablets in 24 hours.
- If you miss a dose, do not take an extra dose. Wait and take your next dose at the regular time. Do not take more than 1 dose of Auvelity at a time.
- Do not change your dose or stop taking Auvelity without talking to your HCP.
- Swallow Auvelity tablets whole. Do not crush, chew, or divide the tablets.
- Do not give Auvelity to other people.
- If you take too much Auvelity call your HCP or seek medical advice promptly.

LEARN MORE

For more information about Auvelity, call 866-496-2976 or visit Auvelity.com.
This summary provides basic information about Auvelity but does not include all information known about this medicine. Read the information that comes with your prescription each time your prescription is filled. This information does not take the place of talking with your doctor. Be sure to talk to your doctor or other HCP about Auvelity and how to take it. Your HCP is the best person to help you decide if Auvelity is right for you.

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Please see full Prescribing Information, including Boxed Warning for suicidal thoughts and behaviors, and Medication Guide.

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 see here for full Prescribing Information

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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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Source: Axsome Therapeutics, Inc.