Axsome Therapeutics Presents Data from Three of Its Innovative Neuroscience Programs at the American Society of Clinical Psychopharmacology (ASCP) 2025 Annual Meeting

May 28, 2025

NEW YORK, May 28, 2025 (GLOBE NEWSWIRE) -- Axsome Therapeutics, Inc. (NASDAQ: AXSM), a biopharmaceutical company leading a new era in the treatment of central nervous system (CNS) disorders, today announced presentations from three of its innovative neuroscience programs at the American Society of Clinical Psychopharmacology (ASCP) 2025 Annual Meeting, being held from May 27-30 in Scottsdale, Arizona.

Details of the presentations are as follows:

AUVELITY

Title: Initiating Dextromethorphan 45 mg - Bupropion 105 mg (AUVELITY®) in Patients with Major Depressive Disorder (MDD): Expert Panel Consensus Recommendations
Lead Author: Anita Clayton, MD, Wilford W. Spradlin Professor and Chair of Psychiatry & Neurobehavioral Sciences and Professor of Clinical Obstetrics & Gynecology at the University of Virginia
Presentation Date and Time: Wednesday, May 28, 11:15 a.m. - 1 p.m. Mountain Standard Time
Session Name: Poster Session I
Poster Number: W25

AXS-05

Title: Efficacy and Safety of AXS-05 in Alzheimer's Disease Agitation: A Phase 3 Randomized-Withdrawal Double-Blind Placebo-Controlled Study
Lead Author: Jeffrey Cummings, MD, ScD, Vice Chair of Research, UNLV Department of Brain Health
Presentation Date and Time: Thursday, May 29, 11:30 a.m. - 1 p.m. Mountain Standard Time
Session Name: Poster Session II
Poster Number: T16

Solriamfetol

Title: Solriamfetol for Excessive Daytime Sleepiness in Patients with Narcolepsy and OSA Reporting Anxiety and Depression in the Real-World SURWEY Study
Lead Author: Ulf Kallweit, MD, Assistant Professor of Neurology at Witten/Herdecke University, Germany
Presentation Date and Time: Thursday, May 29, 11:30 a.m. - 1 p.m. Mountain Standard Time
Session Name: Poster Session II
Poster Number: T15

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 Axsome Therapeutics

Axsome Therapeutics is a biopharmaceutical company leading a new era in the treatment of central nervous system (CNS) conditions. We deliver scientific breakthroughs by identifying critical gaps in care and develop differentiated products with a focus on novel mechanisms of action that enable meaningful advancements in patient outcomes. Our industry-leading neuroscience portfolio includes FDA-approved treatments for major depressive disorder, excessive daytime sleepiness associated with narcolepsy and obstructive sleep apnea, and migraine, and multiple late-stage development programs addressing a broad range of serious neurological and psychiatric conditions that impact over 150 million people in the United States. Together, we are on a mission to solve some of the brain's biggest problems so patients and their loved ones can flourish. For more information, please visit us at **www.axsome.com** and follow us on **LinkedIn** and **X**.

Forward Looking Statements

Certain matters discussed in this press release are "forward-looking statements". The Company 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 commercial success of the Company's SUNOSI ®, AUVELITY®, and SYMBRAVO® products and the success of the Company's efforts to obtain any additional indication(s) with respect to solriamfetol and/or AXS-05; the Company's ability to maintain and expand payer coverage; the success, timing and cost of the Company's ongoing clinical trials and anticipated clinical trials for the Company's current product candidates, including statements regarding the timing of initiation, pace of enrollment and completion of the trials (including the Company's ability to fully fund the Company's disclosed clinical trials, which assumes no material changes to the Company's currently projected revenues or expenses), futility analyses and receipt of interim results, which are not necessarily indicative of the final results of the Company's ongoing clinical trials, and/or data readouts, 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 the Company's current product candidates; the Company's ability to fund additional clinical trials to continue the advancement of the Company's product candidates; the timing of and the Company's ability to obtain and maintain U.S. Food and Drug Administration ("FDA") or other regulatory authority approval of, or other action with respect to, the Company's product candidates, including statements regarding the timing of any NDA submission; 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 Company's ability to successfully resolve any intellectual property litigation, and even if such disputes are settled, whether the applicable federal agencies will approve of such settlements; 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 commercialization of SUNOSI, AUVELITY, and SYMBRAVO and for the Company's commercial launch of its other product candidates, if approved, and the potential impact on the Company's anticipated cash runway; the Company's ability to convert sales to recognized revenue and maintain a favorable gross to net sales; unforeseen circumstances or other disruptions to normal business operations arising from or related to domestic political climate, geo-political conflicts or a global pandemic 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 circumstances.

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