Axsome Therapeutics Announces Results of CRESCENDO Narcolepsy Patient Survey Demonstrating Unmet Needs in Treated Narcolepsy Type 1 Patients

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77% of narcolepsy type 1 patients continue to experience cataplexy attacks despite being treated

64% of narcolepsy type 1 patients continue to experience excessive daytime sleepiness, as assessed by the Epworth Sleepiness Scale (ESS), despite being treated

74% of treated narcolepsy type 1 patients exhibit cognitive impairment, as assessed by the British Columbia Cognitive Complaints Inventory (BC-CCI)

Depression and anxiety were experienced by 45% and 57% of narcolepsy type 1 patients, respectively

NEW YORK, March 25, 2024 (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 topline results from the CRESCENDO (Characterizing Patient Perspectives on Unmet Needs in Narcolepsy) survey of patients with narcolepsy type 1 (NT1, i.e., narcolepsy with cataplexy) receiving treatment, demonstrating high rates of persistent symptoms and significant patient burden, despite being on current treatments. CRESCENDO was conducted in partnership with Narcolepsy Network, a national non-profit patient support organization for people with narcolepsy, idiopathic hypersomnia, and related sleep disorders.

The CRESCENDO survey included 203 adult patients diagnosed with NT1, who collectively have more than 2600 years of lived experience with the sleep disorder, to understand their experience and journey, to measure disease symptoms including cognitive impairment while on treatment, and to assess burden of illness, comorbidities, and unmet needs and challenges patients face. To quantify key elements of the narcolepsy patient experience, CRESCENDO utilized patient reported measures, and validated scales including the Epworth Sleepiness Scale (ESS) to assess excessive daytime sleepiness (EDS), and the British Columbia Cognitive Complaints Inventory (BC-CCI) to assess cognitive function.

All patients taking part in the survey were currently undergoing treatment for NT1. The most common treatments were wake promoting agents (about 53% of surveyed patients), oxybates (47%), and stimulants (42%).

“Narcolepsy is a debilitating and incurable orphan neurologic disorder. Its most troublesome symptom is daytime sleepiness, which can impair social and occupational functioning and can cause potentially dangerous sleep attacks. Its other symptoms include cataplexy, episodes in which strong emotion causes a sudden loss of muscle control, sleep paralysis, sleep-related hallucinations, and disrupted nighttime sleep,” said Dr. Karl Doghramji, Professor of Psychiatry, Neurology and Medicine, and Medical Director of the Jefferson Sleep Disorders Center at Thomas Jefferson University in Philadelphia, PA. “Unfortunately, narcolepsy is underrecognized and underdiagnosed by the medical community and its burden of illness is not widely understood or appreciated, which is why the CRESCENDO survey is such an important step forward in raising awareness of narcolepsy and its impact on patient lives, and in giving voice to the thousands of individuals living with this debilitating disorder.”

Despite receiving treatment, the majority of narcolepsy patients continued to experience symptoms. Cataplexy was reported by 77% of patients while on their current treatment regimen. EDS, assessed using the ESS (scores > 10), was observed in 64% of patients despite receiving current treatments. Cognitive impairment, assessed using the BC-CCI (scores ≥5), was observed in 74% of patients. Depression and anxiety were experienced by about 45% and 57% of patients respectively.

Axsome plans to present the detailed results of the CRESCENDO survey at upcoming scientific meetings.

Key Topline Findings from the CRESCENDO Survey

Patient Demographics

- Survey respondents consisted of a total of 203 adults, aged 18-82 years (mean 41 years) with a diagnosis of narcolepsy Type 1, all of whom had experience with FDA-approved treatments for their narcolepsy.

Current Treatments and Comorbidities

- Subjects were receiving pharmacotherapy for narcolepsy.
- The most common narcolepsy-specific treatments were wake promoting agents (53% of surveyed patients), oxybates (47%), and stimulants (42%).
- 37% of participants were diagnosed with depression, of which 80% were taking medication to manage their depression.

- 37% of participants were diagnosed with anxiety, of which 72% were taking medication to manage their anxiety.

Prevalence of Narcolepsy Symptoms While on Treatment

- Cataplexy was reported by 77% of patients while on their current treatment regimen.
- EDS, assessed using the ESS (scores > 10), was observed in 64% of patients despite receiving current treatments.
- Cognitive impairment, assessed using the BC-CCI (scores ≥5), was observed in 74% of patients on treatment.
- 68% rated their ability to concentrate as poor, very poor, or average.

Cataplexy Impacts on Daily Life

- 65% of participants currently experiencing cataplexy reported that cataplexy burdens their professional life (e.g. career, school), despite treatment
- 60% of participants currently experiencing cataplexy reported that cataplexy burdens their social life, despite treatment.
- 50% of patients currently experiencing cataplexy reported that cataplexy burdens their day-to-day life, despite treatment
- 64% and 68% of patients experiencing cataplexy reported being embarrassed by falling down and slurred speech, respectively, despite treatment.

Time of Conduct

- The survey was conducted between October-December 2023.

About Narcolepsy

Narcolepsy is a serious and debilitating orphan neurological condition that causes dysregulation of the sleep-wake cycle and is characterized clinically by excessive daytime sleepiness, cataplexy, hypnagogic hallucinations, sleep paralysis, and disrupted nocturnal sleep. A majority of narcolepsy patients report cognitive impairment related to their condition. Cataplexy is seen in an estimated 70% of narcolepsy patients and is a sudden reduction or loss of muscle tone while a patient is awake, typically triggered by strong emotions such as laughter, fear, anger, stress, or excitement. Narcolepsy interferes with cognitive, psychological, and social functioning, increases the risk of work- and driving-related accidents, and is associated with a 1.5-fold higher mortality rate.

About Narcolepsy Network

Narcolepsy Network is a 501(c)(3), member-led community organization based in the United States that works to educate, empower, and connect people impacted by narcolepsy, idiopathic hypersomnia and related sleep disorders. Through the lens of advocacy, education, awareness, and support, Narcolepsy Network delivers programs and resources by sharing clinical updates and research, hosting educational webinars, facilitating support groups, and providing advocacy opportunities. Narcolepsy Network works with industry to ensure a neutral and unbiased approach to engage with the patient community. - Neutrality Statement (narcolepsynetwork.org)

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 revenues or expenses), futility analyses and receipt of interim results, which are not necessarily indicative of the final results of our 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 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 statements regarding the timing of any NDA submission; 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, if approved, 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 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 circumstance.

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