Neumora Therapeutics Announces Positive Results from NMRA-511 Phase 1b Signal-Seeking Study in Alzheimer's Disease Agitation

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NMRA-511 demonstrated a 15.7 reduction on mean CMAI total score, representing a clinically meaningful effect

NMRA-511 demonstrated unsurpassed clinical effect size on CMAI total score in a pre-specified population with elevated anxiety

NMRA-511 demonstrated a favorable tolerability and safety profile

Neumora plans to evaluate higher doses of NMRA-511 via initiation of a multiple ascending dose expansion cohort in 2026

Company to host conference call today at 8:00 am ET

WATERTOWN, Mass., Jan. 05, 2026 (GLOBE NEWSWIRE) -- **Neumora Therapeutics, Inc.** (Nasdaq: NMRA), a clinical-stage biopharmaceutical company with a therapeutics pipeline consisting of programs that target novel mechanisms of action for a broad range of underserved, prevalent diseases, today announced positive results from its Phase 1b signal-seeking study of NMRA-511 in people with Alzheimer's disease (AD) agitation. NMRA-511, an oral, highly potent, brain-penetrant and selective antagonist of the vasopressin 1a receptor (V1aR) met the goal of the Phase 1b study, demonstrating a clinically meaningful effect size in people with AD agitation. In the study, NMRA-511 demonstrated a favorable tolerability and safety profile with no reports of somnolence or sedation.

"The goal of this signal-seeking study was to investigate the clinical potential of NMRA-511 in AD agitation and to identify a clinical effect size to inform further development. It has achieved that goal, demonstrating a clinically meaningful and robust effect in a broad patient population. We are encouraged by these data, which demonstrate a clear clinical effect that NMRA-511 meaningfully improves agitation symptoms among people with AD agitation, and has an unsurpassed effect size among patients with higher levels of baseline anxiety, with a favorable safety and tolerability profile" said Bill Aurora, Pharm.D., chief operating and development officer, Neumora. "Anxiety is often an underlying symptom that is present early in the AD agitation disease course, and there is an unmet need for tolerable therapies that can reduce agitation and anxiety symptoms. We look forward to advancing the program and exploring higher doses of NMRA-511. Our deepest thanks go to the patients who participated in this study, their families, the dedicated investigators and others who contributed to the important work of developing better treatments for this devastating condition."

"AD agitation is a common and distressing symptom in Alzheimer's dementia that can significantly impact the quality of life for both patients and caregivers. It is associated with increased morbidity and mortality and earlier placement in long-term care facilities. Existing treatment options are often limited by modest efficacy, tolerability and safety concerns, leaving vast unmet need for therapies that reduce agitation, and improve outcomes without significant adverse effects," said Anton P. Porsteinsson, M.D., William B. and Sheila Konar Professor of Psychiatry, Neurology, Neuroscience, and Medicine; Director, Alzheimer's Disease Care, Research and Education Program (AD-CARE), University of Rochester School of Medicine and Dentistry. "The results of treatment with NMRA-511 are particularly encouraging, as they demonstrated clinically meaningful effects in agitation symptoms among people with AD agitation, and even more profound results among those with elevated anxiety – representing a significant number of treated patients. These results are particularly compelling given the favorable tolerability profile, and as they are clearly supported by the understood link between the vasopressin system and regulation of anxiety."

PHASE 1b RESULTS SUMMARY

The Phase 1b study investigated NMRA-511 in healthy elderly adult participants (Part A) as well as people with agitation associated with dementia due to AD (Part B). Part A was a randomized, double-blind, placebo-controlled cohort designed to evaluate the safety, tolerability and pharmacokinetics of NMRA-511 in eight healthy elderly participants. Part B was a multicenter, randomized, double-blind, placebo-controlled, parallel-group cohort designed to evaluate the safety, tolerability, and efficacy of NMRA-511 20 mg twice-daily (BID) in 80 people with AD agitation. The Phase 1b study was designed as a signal-seeking study to demonstrate a clinical effect and was not powered for statistical significance.

Key findings from Part B of the Phase 1b study include:

- 71 patients were included in the efficacy analysis (the modified analysis set [MAS[i]]).
- 36 patients were included in the pre-specified sub-population of patients with elevated anxiety at baseline (Rating Anxiety in Dementia score ≥12).
- In the MAS, patients treated with NMRA-511 demonstrated a -2.6 and -2.1 placebo-adjusted change from baseline on CMAI total score at Weeks 6 and 8 respectively, representing a Cohen's d effect size range of 0.20 – 0.23.
- In the elevated anxiety population, NMRA-511 demonstrated a -7.6 and -5.6 placebo-adjusted change from baseline on CMAI total score at Weeks 6 and 8 respectively, representing a Cohen's d effect size range of 0.51 – 0.64.
- NMRA-511 demonstrate a favorable tolerability and safety profile. Treatment emergent adverse events (TEAEs) were typically mild to moderate in severity, and there were low treatment discontinuations due to TEAEs (2.5%).

- The most common adverse effects (>5% in either treatment group) in the study were nasopharyngitis, urinary tract infection, anemia, arthralgia, diarrhea, dizziness, headache, hyponatremia, myalgia, nausea, vomiting and abdominal pain.

NEXT STEPS

Neumora intends to advance the development of NMRA-511. The following next steps are planned for the program:

- Initiate a multiple ascending dose extension study investigating higher doses of NMRA-511 in 2026.
- Formulation development to enable once-daily dosing via an extended-release formulation of NMRA-511 in 2026.
- Initiate a Phase 2/3 dose ranging study with NMRA-511.

Webcast Information
Neumora will host a conference call at 8:00 a.m. ET on January 5, 2026. Participants can register for the live webcast here. In addition, a replay of the conference call will be available on the events and presentations section of the Company's website at www.neumoratx.com. A replay of the webcast will be available following the completion of the event and will be archived for up to 30 days.

About NMRA-511
NMRA-511 is a highly potent and selective, best-in-class investigational antagonist of the vasopressin 1a receptor (V1aR) that exhibited greater than 3,000-fold selectivity over the V1b and V2 receptors and approximately 300-fold selectivity over the oxytocin receptor in preclinical studies. The V1aR is known to play a role in regulation of aggression, affiliation, stress and anxiety response and several lines of evidence, and the Phase 1b data reported today, indicate that V1aR antagonists have therapeutic potential for reducing symptoms of agitation. Based on data available to date, Neumora believes NMRA-511 has the potential to be a promising novel medication for multiple neuropsychiatric disorders and neurodegenerative diseases across the spectrum of anxiety, aggression and stress.

About Neumora
Neumora Therapeutics, Inc. is a clinical-stage biopharmaceutical company founded to confront the greatest medical challenges of our generation by taking a fundamentally different approach to the way treatments for brain diseases are developed. Our therapeutic pipeline currently consists of seven programs that target novel mechanisms of action for a broad range of underserved, prevalent diseases. Neumora's mission is to redefine neuroscience drug development by bringing forward the next generation of novel therapies that offer improved treatment outcomes and quality of life for patients.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements about Neumora Therapeutics, Inc. (the "Company," "we," "us," or "our") within the meaning of the federal securities laws, including statements related to: Neumora's intention to redefine neuroscience drug development by bringing forward the next generation of novel therapies that offer improved treatment outcomes and quality of life for patients; NMRA-511's potential to meaningfully improve agitation symptoms among people with AD agitation and efficacy among patients with higher levels of baseline anxiety and potential differentiation from standard of care; the therapeutic potential of V1aR antagonists for reducing symptoms of agitation; the timing, progress and plans for its therapeutic development programs, including advancement of the development of NMRA-511 ; and other statements identified by words such as "could," "expects," "intends," "may," "plans," "potential," "should," "will," "would," or similar expressions and the negatives of those terms. Other than statements of historical facts, all statements contained in this press release are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These statements are subject to risks and uncertainties that could cause the actual results to be materially different from the information expressed or implied by these forward-looking statements, including, among others: comparisons to efficacy results from other sponsors should be interpreted with caution due to differences in compounds, study designs, subject characteristics and other factors that may limit direct comparability; the risks related to the inherent uncertainty of clinical drug development and unpredictability and lengthy process for obtaining regulatory approvals; risks related to the timely initiation and enrollment in our clinical trials; risks related to our reliance on third parties, including contract research organizations; risks related to serious or undesirable side effects of our therapeutic candidates; risks related to our ability to utilize and protect our intellectual property rights; and other matters that could affect sufficiency of capital resources to fund operations. For a detailed discussion of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Neumora's business in general, please refer to the risk factors identified in the Company's filings with the Securities and Exchange Commission (SEC), including but not limited to its Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, which was filed with the SEC on November 6, 2025. Forward-looking statements speak only as of the date hereof, and, except as required by law, Neumora undertakes no obligation to update or revise these forward-looking statements.

Neumora Contact:
Helen Rubinstein
617-402-5700
Helen.Rubinstein@neumoratx.com

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[i]Modified Analysis Set: 2 placebo patients excluded based on rater change driving outlier data (>3 standard deviations from the mean).