Neumora Therapeutics Announces Clinical Hold of Phase 1 NMRA-266 Study

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WATERTOWN, Mass., April 15, 2024 (GLOBE NEWSWIRE) -- **Neumora Therapeutics, Inc.** (Nasdaq: NMRA), a clinical-stage biopharmaceutical company with a therapeutics pipeline consisting of seven clinical and pre-clinical brain disease programs, today announced that the Phase 1 trial of NMRA-266 has been placed on clinical hold by the U.S. Food and Drug Administration (FDA). NMRA-266 is a positive allosteric modulator (PAM) of the M4 muscarinic receptor and is part of the Company's M4 PAM franchise. The clinical hold determination follows recently available pre-clinical data showing convulsions in rabbits.

Following this action, the Phase 1 single ascending dose / multiple ascending dose study with NMRA-266 has been paused. Approximately 30 participants have been dosed in the Phase 1 study, with no evidence of convulsions observed in any participant.

Neumora is working with the FDA to evaluate the potential to resolve the clinical hold. While these discussions with the Agency are ongoing, the Company's prior guidance regarding NMRA-266 is no longer applicable. Neumora will provide an update on NMRA-266 when available.

Neumora's M4 franchise includes multiple novel compounds beyond NMRA-266 that each have different properties and chemical composition. These compounds demonstrated robust activity in preclinical efficacy models, as well as high selectivity for the M4 receptor subtype and the potential for an oral once-daily dosing profile. Neumora is advancing pre-clinical safety and toxicology work with these compounds and expects to submit an IND in 2025.

"We are disappointed with the unanticipated safety findings in rabbits and are discussing next steps with the FDA," said Henry Gosebruch, president and chief executive officer, Neumora. "In parallel, we're continuing to make significant progress across the rest of our portfolio as we seek to fulfill our mission to develop medicines for serious brain diseases. We anticipate several important milestones including Phase 3 data in major depressive disorder and the initiation of a Phase 2 study in bipolar depression with navacaprant, our kappa opioid receptor antagonist, and the initiation of a Phase 1b study in agitation in Alzheimer's disease with NMRA-511, our vasopressin 1a receptor antagonist."

About Neumora
Neumora Therapeutics, Inc. is a clinical-stage biopharmaceutical company founded to confront the global brain disease crisis by taking a fundamentally different approach to the way treatments for brain diseases are developed. Our therapeutic pipeline currently consists of seven clinical and preclinical neuroscience programs that target novel mechanisms of action for a broad range of underserved neuropsychiatric disorders and neurodegenerative diseases. Our work is supported by an integrated suite of translational, clinical, and computational tools to generate insights that can enable precision medicine approaches. 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 suffering from brain diseases.

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 suffering from brain diseases; the timing, progress and plans for its therapeutic development programs, including the timing of initiation and data read outs for its programs and studies, as well as its clinical trial and development plans; Neumora's ability to work with the FDA to resolve the clinical hold; the potential for Neumora to advance other compounds in its M4 portfolio; the oral one-daily dosing potential of any M4 compounds; the timing and potential for any INDs in Neumora's M4 portfolio; 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 or to be materially different from the information expressed or implied by these forward-looking statements, including, among others: 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 CROs; 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 Annual Report on Form 10-K for the year ended December 31, 2023 that was filed with the SEC on March 7, 2024. 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.

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