Neumora Therapeutics Announces NMRA-266 IND Clearance and Initiation of Phase 1 Clinical Study

November 27, 2023 12:00 PM EST

NMRA-266 is a highly selective positive allosteric modulator of the M4 muscarinic receptor, a clinically validated target for the treatment of schizophrenia

WATERTOWN, Mass., Nov. 27, 2023 (GLOBE NEWSWIRE) -- **Neumora Therapeutics, Inc.** (Neumora), a clinical-stage biopharmaceutical company redefining neuroscience drug development, today announced the initiation of a Phase 1 single ascending dose / multiple ascending dose study evaluating NMRA-266 in healthy adult participants. NMRA-266 is a highly selective positive allosteric modulator of the M4 muscarinic receptor that Neumora is developing as a treatment for schizophrenia and other neuropsychiatric disorders.

“The initiation of this Phase 1 study is an important step in the development of NMRA-266. In pre-clinical studies NMRA-266 demonstrated a favorable pharmacologic profile that includes high potency and selectivity for the M4 receptor subtype, meriting its advancement into the clinic,” said Robert Lenz, M.D. Ph.D., executive vice president and head of research and development, Neumora. “With its pre-clinical profile and clinical validation of the M4 muscarinic receptor class in treating schizophrenia, we believe that NMRA-266 has strong potential as a treatment for neuropsychiatric disorders.”

Neumora believes that as a selective M4 receptor-positive allosteric modulator, NMRA-266 has the potential to deliver antipsychotic efficacy, while minimizing the side effects associated with current antipsychotics and other non-selective muscarinic agonists.

“Muscarinic receptor-targeting compounds have demonstrated robust activity in multiple clinical trials, reinforcing the potential of this class of medicines as an approach to treating schizophrenia and other neuropsychiatric disorders,” said John H. Krystal, M.D., Robert L. McNeil, Jr. Professor of Translational Research and Professor of Psychiatry, of Neuroscience, and Psychology, and chair of the Yale Department of Psychiatry at Yale School of Medicine. “Schizophrenia is a serious and debilitating disorder. Limitations in the effectiveness of existing treatments result in significant unmet medical need. Pharmacologic treatment is an integral part of a comprehensive treatment plan, and finding the right treatment option for each patient is vitally important. As such, it’s encouraging to see the development of multiple products within the muscarinic class that may help people with schizophrenia find a treatment that works for them.”

About NMRA-266
NMRA-266 is an investigational positive allosteric modulator of the M4 muscarinic receptor subtype. While current antipsychotics approved for schizophrenia work primarily by blocking D2 dopamine receptors, growing evidence supports the approach of targeting the M4 muscarinic receptor to elicit antipsychotic effects, without the side effects associated with the first- and second-generation antipsychotics. M4 muscarinic receptor-targeting compounds have shown robust antipsychotic activity in multiple, placebo-controlled clinical trials, demonstrating potential as an approach to treating schizophrenia. Neumora exclusively licensed certain intellectual property rights related to NMRA-266 from Vanderbilt University, including composition of matter patent extending to 2042.

About Schizophrenia
Schizophrenia is a debilitating neuropsychiatric disorder characterized by positive symptoms (such as delusions and hallucinations), negative symptoms (such as diminished emotional expression) and cognitive symptoms (such as deficits in types of memory) that impacts approximately 3 million adults in the United States. Currently approved therapies for schizophrenia are often associated with potentially serious side effects, including movement and metabolic effects, and no therapies with a novel mechanism of action have been recently approved. Significant unmet medical need remains in the treatment of schizophrenia as a result of this paradigm. A study conducted by the National Institute of Mental Health found that approximately 75 percent of people with schizophrenia discontinue medication within 18 months due in part to inefficacy or intolerable side effects.

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; the potential for NMRA-266 to be a treatment for schizophrenia and other neuropsychiatric disorders; the expected timing of patent protection for NMRA-266 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 Registration Statement on Form S-1, as

amended (File No. 333-274229), filed with the SEC on September 11, 2023, and related Prospectus dated September 14, 2023 filed under 424(b)(4) of the Securities Act of 1933, as amended. 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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