MediciNova Provides Enrollment Update for Ongoing ALS and Hypertriglyceridemia Clinical Trials

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MN-166 COMBAT ALS trial down to single digit required enrollment while MN-001 hypertriglyceridemia trial in type 2 diabetes patients requires final two patients

LA JOLLA, Calif., July 24, 2025 (GLOBE NEWSWIRE) -- MediciNova, Inc., a biopharmaceutical company traded on the NASDAQ Global Market (NASDAQ:MNOV) and the Standard Market of the Tokyo Stock Exchange (Code Number: 4875) (the “Company”), today provides an update on the enrollment of two key ongoing clinical trials for the Company’s developmental compounds MN-166 (ibudilast) and MN-001 (tipelukast), each of which is poised to complete randomization.

Specifically, the Company is now down to single digit required randomization in its ongoing Phase 2/3 COMBAT-ALS trial. Concurrently, the Company is seeking the final two randomized subjects for its Phase 2 trial in patients with dyslipidemia and fatty liver disease due to type 2 diabetes.

Dr. Yuichi Iwaki, MediciNova President and CEO, commented, "We are pleased to report continued strong progress in our core COMBAT-ALS program. Following the release of interim results last year, we are now approaching the completion of patient randomization—a key milestone in the study. Our MN-166 ALS program continues to generate significant interest and anticipation within the ALS community. In parallel, the large Expanded Access Program (EAP), supported by a $22 million grant from the NIH, is steadily enrolling patients. We are actively preparing for regulatory discussions with the FDA, with top-line data anticipated by the end of next year. Further, we believe additional opportunities exist for our MN-001 compound in dyslipidemia and fatty liver disease patients due to type-2 diabetes. We believe each of these programs address highly unmet medical needs in very difficult-to-treat conditions, and we look forward to providing additional outcomes from each of these trials as results become available.”

About MN-166 (ibudilast)

MN-166 (ibudilast) is an orally available small molecule compound that inhibits phosphodiesterase type-4 (PDE4) and inflammatory cytokines, including macrophage migration inhibitory factor (MIF). It is in late-stage clinical development for the treatment of neurodegenerative diseases such as ALS (amyotrophic lateral sclerosis), progressive MS (multiple sclerosis), and DCM (degenerative cervical myelopathy); and is also in development for glioblastoma, Long COVID, CIPN (chemotherapy-induced peripheral neuropathy), and substance use disorder. In addition, MN-166 was evaluated in patients that are at risk for developing acute respiratory distress syndrome (ARDS). MediciNova holds Orphan Drug Designation for MN-166 in ALS by U.S. FDA and EU EMA. MN-166 has received Fast Track Designation by FDA for treatment of ALS. In addition, MN-166 holds Orphan Disease Designation for the treatment of Glioblastoma.

About MN-001 (tipelukast)

MN-001 (tipelukast) is a novel, orally bioavailable, small molecule compound thought to exert its effects through several mechanisms to produce its anti-inflammatory and anti-fibrotic activity in preclinical models, including leukotriene (LT) receptor antagonism, inhibition of phosphodiesterases (PDE) (mainly 3 and 4), and inhibition of 5-lipoxygenase (5-LO). The 5-LO/LT pathway has been postulated as a pathogenic factor in fibrosis development, and MN-001's inhibitory effect on 5-LO and the 5-LO/LT pathway is a novel approach to treat fibrosis. MN-001 has been shown to down-regulate expression of genes that promote fibrosis including LOXL2, Collagen Type 1 and TIMP-1. MN-001 has also been shown to down-regulate expression of genes that promote inflammation including CCR2 and MCP-1. In addition, MN-001 was found to inhibit triglyceride synthesis in hepatocytes by inhibiting arachidonic acid uptake.

About MediciNova

MediciNova, Inc. is a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of serious diseases with unmet medical needs and a commercial focus on the United States (U.S.) market. The company’s current strategy is to focus their development activities on MN-166 (ibudilast) for neurological and other disorders such as amyotrophic lateral sclerosis (ALS), progressive multiple sclerosis (MS), chemotherapy-induced peripheral neuropathy, degenerative cervical myelopathy, glioblastoma, substance dependence and addiction (e.g., methamphetamine dependence, opioid dependence, and alcohol dependence), prevention of acute respiratory distress syndrome (ARDS), and Long COVID, and MN-001 (tipelukast) for fibrotic and other metabolic disorders such as nonalcoholic fatty liver disease (NAFLD) and hypertriglyceridemia. The company intends to advance their pipeline through a combination of investigator-sponsored clinical trials, trials funded through government grants or other grants, trials funded on their own, or through strategic alliances to help support further clinical development of their lead programs.

Forward-Looking Statements

Statements in this press release that are not historical in nature constitute forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, statements regarding the future development and efficacy of MN-166 and MN-001. These forward-looking statements may be preceded by, followed by, or otherwise include the words "believes," "expects," "anticipates," "intends," "estimates," "projects," "can," "could," "may," "will," "would," “considering,” “planning” or similar expressions. These forward-looking statements involve a number of risks and uncertainties that may cause actual results or events to differ materially from those expressed or implied by such forward-looking statements. Factors that may cause actual results or events to differ materially from those expressed or implied by these forward-looking statements include, but are not limited to, risks of obtaining future partner or grant funding for development of MN-166 and MN-001, and risks of raising sufficient capital when needed to fund MediciNova's operations and contribution to clinical development, risks and uncertainties inherent in clinical trials, including the potential cost, expected timing and risks associated with clinical trials designed to meet FDA guidance and the viability of further development considering these factors, product development and commercialization risks, the uncertainty of whether the results of clinical trials will be predictive of results in later stages of product development, the risk of delays or failure to obtain or maintain regulatory approval, risks associated with the reliance on third parties to sponsor and fund clinical trials, risks regarding intellectual property rights in product candidates and the ability to defend and enforce such intellectual property rights, the risk of failure of the third parties upon whom MediciNova relies to conduct its clinical trials and manufacture its product candidates to perform as expected, the risk of increased cost and

delays due to delays in the commencement, enrollment, completion or analysis of clinical trials or significant issues regarding the adequacy of clinical trial designs or the execution of clinical trials, and the timing of expected filings with the regulatory authorities, MediciNova's collaborations with third parties, the availability of funds to complete product development plans and MediciNova's ability to obtain third party funding for programs and raise sufficient capital when needed, and the other risks and uncertainties described in MediciNova's filings with the Securities and Exchange Commission, including its annual report on Form 10-K for the year ended December 31, 2024 and its subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Undue reliance should not be placed on these forward-looking statements, which speak only as of the date hereof. MediciNova disclaims any intent or obligation to revise or update these forward-looking statements.

INVESTOR CONTACT:

David H. Crean, Ph.D.
Chief Business Officer
MediciNova, Inc
info@medicinova.com

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