



MediciNova Announces Completion of Patient Enrollment in COMBAT-ALS Phase 2b/3 Clinical Trial of MN-166 (ibudilast)

September 22, 2025

~Patient Recruitment Closed~

LA JOLLA, Calif., Sept. 22, 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), today announced the successful completion of patient enrollment in its Phase 2/3 clinical trial, COMBAT-ALS, evaluating MN-166 (ibudilast) for the treatment of Amyotrophic Lateral Sclerosis (ALS). A total of 234 patients have been randomized across two treatment arms at multiple clinical sites in the United States and Canada. Patient recruitment is now officially closed.

MN-166 (ibudilast) is an orally administered small molecule designed to modulate neuroinflammation and oxidative stress pathways implicated in ALS progression. The COMBAT-ALS study is a randomized, double-blind, placebo-controlled trial designed to assess the efficacy, safety, and tolerability of MN-166 over a 12-month treatment period followed by 6-month open-label treatment period.

The trial's primary endpoint is the Combined Assessment of Function and Survival (CAFS). Secondary endpoints include ALSFRS-R score progression, muscle strength measured by hand-held dynamometry, and quality of life assessments. Top-line data are expected by the end of 2026.

MN-166 has previously demonstrated promising results in preclinical models and earlier Phase 1/2 and Phase 2 studies, showing a favorable safety profile and a higher proportion of treatment responders among MN-166-treated patients. The compound has received Orphan Drug Designation and Fast Track Designation from the U.S. Food and Drug Administration (FDA), as well as Orphan Designation from the European Medicines Agency (EMA).

"Completing enrollment in this Phase 2b/3 trial marks a major milestone for our MN-166 program and reflects the dedication of our clinical team and the ALS community," said Dr. Kazuko Matsuda, Chief Medical Officer of MediciNova. "We are deeply grateful to the patients and families participating in this study and look forward to advancing MN-166 (ibudilast) toward potential regulatory submission."

"ALS remains a devastating disease with limited treatment options," said Dr. Yuichi Iwaki, President and Chief Executive Officer of MediciNova. "We are hopeful that MN-166 may offer a meaningful therapeutic advance for patients living with ALS."

About MN-166 (ibudilast)

MN-166 (ibudilast) is a 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 (ibudilast) was evaluated in patients that are at risk for developing acute respiratory distress syndrome (ARDS).

About MediciNova

MediciNova, Inc. is a clinical-stage biopharmaceutical company developing a broad late-stage pipeline of novel small molecule therapies for inflammatory, fibrotic, and neurodegenerative diseases. Based on two compounds, MN-166 (ibudilast) and MN-001 (tipelukast), with multiple mechanisms of action and strong safety profiles, MediciNova has 11 programs in clinical development. MediciNova's lead asset, MN-166 (ibudilast), is currently in Phase 3 for amyotrophic lateral sclerosis (ALS) and degenerative cervical myelopathy (DCM) and is Phase 3-ready for progressive multiple sclerosis (MS). MN-166 (ibudilast) is also being evaluated in Phase 2 trials in Long COVID and substance dependence. MN-001 (tipelukast) was evaluated in a Phase 2 trial in idiopathic pulmonary fibrosis (IPF) and a second Phase 2 trial in non-alcoholic fatty liver disease (NAFLD) is ongoing. MediciNova has a strong track record of securing investigator-sponsored clinical trials funded through government grants.

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.

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