MediciNova Announces Completion of Last Patient, Last Visit in the Double-Blind Portion of the Phase 2b/3 COMBAT-ALS Trial of MN-166 (Ibudilast)

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LA JOLLA, Calif., Sept. 24, 2026 (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 completion of the last patient, last visit (LPLV) in the double-blind portion of COMBAT-ALS, a Phase 2b/3 clinical trial evaluating MN-166 (ibudilast) for the treatment of Amyotrophic Lateral Sclerosis (ALS). A total of 234 participants were randomized to two treatment arms at clinical sites in the United States and Canada. Participants who remain active in the study are continuing treatment with MN-166 in the Open-Label Extension phase. The LPLV for the entire study is expected in March 2027. MediciNova expects to report topline results from the double-blind portion of the study by the end of 2026.

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

The trial's primary endpoint is the Combined Assessment of Function and Survival (CAFS). Secondary endpoints include change in the ALS Functional Rating Scale–Revised (ALSFRS-R), muscle strength measured by hand-held dynamometry, and quality-of-life assessments.

MN-166 has demonstrated a favorable safety profile in prior Phase 1/2 and Phase 2 clinical studies, with earlier studies also showing a higher proportion of treatment responders among participants who received MN-166. MN-166 has received Fast Track designation and Orphan Drug designation from the U.S. Food and Drug Administration (FDA), as well as orphan designation from the European Medicines Agency (EMA).

Yuichi Iwaki, M.D., Ph.D., President and Chief Executive Officer of MediciNova, commented: "Completion of the last patient's final visit in the double-blind portion of COMBAT-ALS marks a significant milestone for our lead clinical program and keeps us on track to report topline results by the end of 2026. With all patient visits now complete in the double-blind portion of the study, our focus is on database lock and rigorous analysis of the study data. We believe COMBAT-ALS has the potential to provide important insight into MN-166 as a treatment option for people living with ALS, a disease with substantial unmet medical need. We are deeply grateful to the participants and their families, caregivers, and care partners, as well as the investigators and clinical site teams whose commitment made this milestone possible."

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 neurodegenerative diseases, including amyotrophic lateral sclerosis (ALS), progressive multiple sclerosis (MS), and degenerative cervical myelopathy (DCM). MN-166 is also in development for glioblastoma, Long COVID, chemotherapy-induced peripheral neuropathy (CIPN), and substance use disorder. In addition, MN-166 has been evaluated in patients at risk of 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 numerous programs in clinical development. MediciNova's lead asset, MN-166 (ibudilast), is currently in late stage trials 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, 2025 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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