MediciNova Announces Update and Basic Characteristic Randomized Patients' of Phase 2/3 Clinical Trial of MN-166 (Ibudilast) in ALS (COMBAT-ALS Clinical Trial) Presented at the 36th International Symposium on ALS/MND

December 8, 2025

LA JOLLA, Calif., Dec. 08, 2025 (GLOBE NEWSWIRE) -- MediciNova, Inc., a biopharmaceutical company listed on the NASDAQ Global Market (NASDAQ: MNOV) and the Standard Market of the Tokyo Stock Exchange (Code: 4875), today announced an update and the patients' basic characteristics data from its Phase 2b/3 clinical trial of MN-166 (ibudilast) in Amyotrophic Lateral Sclerosis (ALS), known as the COMBAT-ALS study. These results were presented at the 36th International Symposium on ALS/MND, held December 5–7, 2025, in San Diego, California, USA.

The poster presentation, titled **"COMBAT-ALS Phase 2b/3 Trial of MN-166 (Ibudilast) in ALS: Trial Update and Basic Characteristics"** (Reference # CTL-21), highlighted the following:

- **Overview of the COMBAT-ALS Clinical Trial:** Purpose, scientific rationale for MN-166 in ALS treatment, study design, and key eligibility criteria.
- **Study Update:** A total of 234 participants were randomized, and enrollment was completed in September 2025.
- **Baseline Characteristics:**
  - Total randomized patients: 234 (Female: 86 [36.8%], Male: 148 [63.2%])
  - Mean age at screening: 60.6 years
  - Racial distribution: Caucasian (90.2%), Asian (5.1%), African American (1.3%), Native Hawaiian or Other Pacific Islander (0.4%), American Indian or Alaskan Native (0.4%), Other (2.6%)
  - ALS onset type: Upper limb (46.2%), Lower limb (32.5%), Bulbar (20.9%), Unknown (0.4%)
  - Mean ALSFRS-R score at screening: 40.6
  - Mean disease duration from first symptom: 12.5 months
  - These demographics and clinical profiles are consistent with other Phase 2 and Phase 3 ALS trials, supporting the generalizability of the study findings.

Dr. Kazuko Matsuda, Chief Medical Officer of MediciNova, commented:
"We would like to express our heartfelt gratitude to the patients, caregivers, and families who made this study possible. Achieving our randomization goal was not without challenges—particularly during the COVID-19 pandemic, which brought unprecedented disruptions to clinical research. Slow enrollment, site restrictions, and uncertainty tested our resilience, but thanks to the dedication of investigators and study teams, we overcame these obstacles together. We anticipate top-line data by the end of 2026 and remain hopeful that MN-166 will represent a meaningful therapeutic advance for patients living with ALS."

Dr. Yuichi Iwaki, President and Chief Executive Officer of MediciNova, added:
"We have been actively supporting patients who wish to continue MN-166 treatment following the COMBAT-ALS study through the FDA's Individual Patient Expanded Access Program, and we remain committed to providing this support going forward. MN-166 was granted Orphan Drug Designation and Fast Track Designation from FDA as well as Orphan Designation by the European Commission for the treatment of ALS. Our clinical development team is working closely with experienced regulatory experts to prepare for the next steps in advancing this program."

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). For the ALS indication, MediciNova has Orphan Drug Designation& Fast Track Status from the US FDA and Orphan Drug Designation from the EMA.

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 Phase 3 for amyotrophic lateral sclerosis (ALS) and degenerative cervical myelopathy (DCM) and is Phase 3-ready for progressive multiple sclerosis (MS). MN-001 (tipelukast) is in a Phase 2 trial treating hypertriglycedemia in type 2 diabetic patients. MediciNova has a strong track record of securing investigator-sponsored clinical trials funded through government grants.

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.

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