MediciNova Presents Study Update and Interim Analysis of Phase 2/3 Clinical Trial of MN-166 (ibudilast) in ALS (COMBAT-ALS Clinical Trial) at the 35th International Symposium on ALS/MND

December 5, 2024

LA JOLLA, Calif., Dec. 05, 2024 (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 announces the study update and interim analysis results from the Company's COMBAT-ALS Phase 2b/3 clinical trial of MN-166 (ibudilast) in Amyotrophic Lateral Sclerosis (ALS) will be presented at the 35th International Symposium on ALS/MND held December 6-8, 2024 in Montreal, Canada.

The highlights of the presentation, titled, "*COMBAT-ALS Phase 2b/3 Trial of MN-166 (Ibudilast) in ALS: Trial Update and Interim Analysis Results" (*Abstract # 302), include:

- Study Update: As of November 15, 2024, a total of 217 participants have been enrolled and 183 participants were assigned to either MN-166 or placebo group.
- Pre-defined interim analysis was conducted to evaluate the correlation between the 6-month and 12-month data and assess the 12-month double-blind phase trial design.
- A subset of patients from the full analysis set who had ALSFRS-R data at 6 months and at least one post-6-month data point. Correlation analysis of the Combined Assessment of Function and Survival (CAFS) scores at 6 and 12 months as well as modified CAFS scores and ALSFRS-R scores were evaluated.
- Positive correlations were observed between the 6-month and 12-month data for CAFS score (0.71), modified CAFS score (0.70), and ALSFRS-R (0.69). [Note: Values in parentheses are Spearman Rank Correlation coefficients]
- Positive correlations were also observed for Bulbar score (0.74), Fine motor score (0.71), and Gross motor score (0.67), but not for Respiratory score. [Note: Values in parentheses are Spearman Rank Correlation coefficients]
- Interim analysis results were reviewed and validated by an external independent Data Safety Monitoring Board (DSMB), which recommended that the trial continue as per the protocol.

MediciNova CMO and Director Kazuko Matsuda commented, "The interim analysis showed a positive correlation between the 6-month and 12-month data. We considered a change in the treatment period, decided to continue the trial with the current treatment plan based on the DSMB's recommendation. We believe these results will be valuable in designing studies for rapidly progressing diseases like ALS. As of mid-November 2024, over 200 patients have been enrolled and more than 180 patients assigned, if we continue to actively enroll in the COMBAT-ALS study, we expect to complete patient assignments by June 2025 with trial results expected in 2026. Concurrently, we have been supporting continued treatment for those patients wishing to continue MN-166 treatment after the 6-month open-label phase via the FDA's Expanded Access Program (EAP). Next year, the NIH-funded, large-scale Expanded Access Program trial is set to begin, and we look forward to the opportunity to provide access to MN-166 to more ALS patients."

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, MN-001, MN-221, and MN-029. 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, MN-001, MN-221, and MN-029 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, 2023 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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