MediciNova Announces MN-166 (ibudilast) Poster Presentation at the 32nd International Symposium on ALS/MND

December 10, 2021

LA JOLLA, Calif., Dec. 10, 2021 (GLOBE NEWSWIRE) -- MediciNova, Inc., a biopharmaceutical company traded on the NASDAQ Global Market (NASDAQ:MNOV) and the JASDAQ Market of the Tokyo Stock Exchange (Code Number: 4875), today announced that Dr. Malath Makhay, Director, Scientific Affairs, presented the poster of MediciNova's ongoing Phase 2b/3 clinical trial of MN-166 (ibudilast) in amyotrophic lateral sclerosis (ALS) at the 32nd International Symposium on ALS/MND (amyotrophic lateral sclerosis/motor neurone disease) being held virtually on December 7 - 10, 2021.

The presentation entitled "**COMBAT-ALS Phase 2b/3 Trial of MN-166 (ibudilast) in ALS: Trial Update**" was given by Malath Makhay, Ph.D., Director, Scientific Affairs, MediciNova, Inc. during the live poster session. In this poster presentation, Dr. Makhay discussed the study objectives, scientific rationale, study design, and demographic and baseline characteristics of the study participants as of August 2021. Additionally, she discussed recently adopted changes including flexibility of riluzole use prior to and during enrollment, and permission to conduct remote clinic visits. These changes were made in order to provide greater opportunity to participate in the trial for patients experiencing tolerability issues while on riluzole treatment and to consider COVID-19 restrictions.

Dr. Yuichi Iwaki, M.D. Ph.D., President and Chief Executive Officer, MediciNova, Inc. commented, "The purpose of presenting ongoing activities from the COMBAT-ALS trial at this symposium is to share information about this important trial with ALS and motor neuron disease researchers, clinicians, patients, families, friends and caregivers. We want to express our deep gratitude to patients who volunteer to participate in our trial, as well as those who conduct the trial at their fine institutions, especially during a tough situation with the COVID-19 outbreak. We have been focused on adding additional sites to this important trial. Now that we have 20 sites actively recruiting patients, we expect the enrollment rate to increase going forward."

About the COMBAT-ALS Trial
This is a Phase 2b/3, multicenter, randomized, double-blind (12 months), placebo-controlled, parallel group study to evaluate the efficacy, safety, and tolerability of MN-166 (ibudilast) followed by an open-label extension phase (6 months) in patients with ALS. Patients who meet entry criteria will be randomly assigned 1:1 to one of two treatment groups, 100 mg/day of MN-166 (ibudilast) or matching placebo. It is planned to enroll 230 subjects at 30 sites in the U.S., Canada, and Europe (NCT04057898). The primary endpoint is change from baseline in ALSFRS-R score at Month 12 (or last observation before death in case of censoring) and survival time. Secondary endpoints include safety and tolerability, responder analysis (stability or improvement in ALSFRS-R score over 12 months), muscle strength, and quality of life. To provide further education on the potential of MN-166 (ibudilast) to treat patients with ALS, an informational webinar presented by MediciNova features Dr. Björn Oskarsson, lead clinical investigator of COMBAT-ALS, and Dr. Benjamin Rix Brooks, who led the first clinical study of MN-166 (ibudilast) in patients with ALS, provides an overview of the drug's mechanism of action, the COMBAT-ALS study design, and findings from the Phase 2 trial in ALS. A replay of the webinar can be viewed here.

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 glioblastoma, patients at risk of developing acute respiratory distress syndrome (ARDS), and substance dependence. MN-001 (tipelukast) was evaluated in a Phase 2 trial in idiopathic pulmonary fibrosis (IPF) and is in preparation for a second Phase 2 trial in nonalcoholic steatohepatitis (NASH). 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, 2020 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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