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

August 30, 2021

LA JOLLA, Calif., Aug. 30, 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 an abstract regarding MediciNova's ongoing Phase 2b/3 clinical trial of MN-166 (ibudilast) in amyotrophic lateral sclerosis (ALS) has been accepted for presentation at the 32nd International Symposium on ALS/MND (amyotrophic lateral sclerosis/motor neurone disease) to be held virtually on December 7 - 10, 2021.

The presentation entitled "***COMBAT-ALS Phase 2b/3 Trial of MN-166 (ibudilast) in ALS: Trial Update***" will be given by Kazuko Matsuda, M.D. Ph.D. M.P.H., Chief Medical Officer, MediciNova, Inc. Presentation details will be disseminated as they become available.

"We are very pleased to present ongoing activities from the COMBAT-ALS trial at the 32nd International Symposium on ALS/MND. The purpose of presenting at this symposium attended by ALS/MND researchers, clinicians, and patients is to share information about this important trial to a greater number of stakeholders in the ALS community. 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," commented Dr. Yuichi Iwaki, M.D. Ph.D., President and Chief Executive Officer, MediciNova, Inc.

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 ALS

Amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease, is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. The nerves lose the ability to trigger specific muscles, which causes the muscles to become weak. As a result, ALS affects voluntary movement and patients in the later stages of the disease may become completely paralyzed. Life expectancy of an ALS patient is usually 2-5 years. According to the ALS Association, there are approximately 16,000 ALS patients in the U.S. and approximately 5,000 people in the U.S. are diagnosed with ALS each year.

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 including ALS, progressive MS (multiple sclerosis), and DCM (degenerative cervical myelopathy); glioblastoma, CIPN (chemotherapy-induced peripheral neuropathy), and substance use disorder. In addition, MN-166 (ibudilast) is being evaluated in patients 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 ALS and DCM and is Phase 3-ready for progressive MS. MN-166 (ibudilast) is also being evaluated in Phase 2 trials in glioblastoma, patients at risk of developing 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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