MediciNova Announces Additional Analyses from Completed Clinical Trial of MN-166 (ibudilast) in ALS Presented at the 30th International Symposium on ALS/MND in Perth, Australia

December 4, 2019

LA JOLLA, Calif., Dec. 04, 2019 (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 additional analyses of MediciNova's completed clinical trial of MN-166 (ibudilast) in ALS (amyotrophic lateral sclerosis), which was conducted at Carolinas HealthCare System's Neuromuscular/ALS-MDA Center at Carolinas HealthCare System Neurosciences Institute, will be presented on December 5, 2019 at 10:30 am local time at the 30th International Symposium on ALS/MND (amyotrophic lateral sclerosis/motor neurone disease) in Perth, Australia.

Highlights of the presentation, entitled "***Interaction (nonuniformity) of ALS Progression and the Efficacy of MN-166 (ibudilast)"***, which will be presented by Kazuko Matsuda, M.D. Ph.D. M.P.H., Chief Medical Officer of MediciNova, Inc., include the following:

- We evaluated the potential background factors of patients' characteristics that could reasonably predict both ALS disease progression and treatment efficacy. These factors included gender, age, race, site of onset (upper limb, lower limb, bulbar onset), UMN (upper motor neuron) / LMN (lower motor neuron) symptom involvement, and ALS history (i.e. days from first onset of symptom to trial enrollment).
- Regression Tree Analysis and Stepwise Regression Analysis were performed to determine which potential factors have an impact on the treatment effect of MN-166 as assessed by the ALSFRS-R score.
- The regression analyses determined that ALS history was a statistically significant factor affecting treatment effect ($p=0.015$).
- Correlational Analysis was conducted to analyze the correlation between (1) ALS history and baseline ALSFRS-R score, and (2) ALS history and disease progression, measured as change in ALSFRS-R score from baseline to end of treatment.
- A significant negative correlation (-0.72, $p<0.01$) was observed between ALS history and baseline ALSFRS-R scores in patients with ALS onset <600 days prior to enrollment (i.e. short ALS history), but not in patients with ALS onset >600 days prior to enrollment (i.e. long ALS history).
- A significant positive correlation (0.63, $p<0.05$) was observed between ALS history and ALS disease progression in the placebo group. With riluzole treatment only (without MN-166 treatment), greater disease progression was observed in short ALS history patients.
- No correlation was observed between ALS history and ALS disease progression in the MN-166 group, which was attributed to the treatment effect in short ALS history patients.
- The results of these analyses indicate that the efficacy of MN-166 is expected to be more robust in patients with a short ALS history.

Yuichi Iwaki, M.D. Ph.D., President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased to present these additional analyses from the completed ALS trial. The conclusions from this work and our other analyses completed previously have already been incorporated into the design of our Phase 3 trial. We believe our improved study design, which includes only ALS subjects with symptom onset of less than 18 months, gives this trial a much higher probability of success."

About the Phase 2 ALS Trial

MediciNova, in collaboration with Dr. Benjamin Rix Brooks, Director, Carolinas Neuromuscular/ALS-MDA Center at Carolinas HealthCare System Neurosciences Institute, evaluated 60 mg of MN-166 (ibudilast) per day in both early and advanced stage ALS patients. All subjects in the study received 100 mg of riluzole per day. This trial was a randomized, double-blind, placebo-controlled study which included a six-month treatment period followed by a six-month open-label extension. The primary endpoint was safety and tolerability and the study also evaluated several efficacy endpoints including functional activity (ALSFRS-R). Data analyzed from the 51 early ALS subjects (the intent-to-treat/ITT population) was presented at the 29th International Symposium on ALS/MND in Glasgow, Scotland, UK in December 2018. There was a higher percentage of responders on the ALSFRS-R total score, MMT (manual muscle testing) and ALSAQ-5 score (subjective quality-of-life questionnaire) in the MN-166 (ibudilast) group compared to the placebo group. This was the first study of MN-166 (ibudilast) in ALS and the study provides the necessary clinical data for powering assumptions for the Phase 3 trial of MN-166 (ibudilast) in ALS.

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 20,000 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 first-in-class, orally bioavailable, small molecule macrophage migration inhibitory factor (MIF) inhibitor and phosphodiesterase

(PDE) -4 and -10 inhibitor that suppresses pro-inflammatory cytokines and promotes neurotrophic factors. It attenuates activated glial cells, which play a major role in certain neurological conditions. MN-166 (ibudilast)'s anti-neuroinflammatory and neuroprotective actions have been demonstrated in preclinical and clinical studies, which provide the rationale for treatment of amyotrophic lateral sclerosis (ALS), progressive multiple sclerosis (MS) and other neurological diseases such as glioblastoma (GBM), and substance abuse/addiction. MediciNova is developing MN-166 for ALS, progressive MS and other neurological conditions such as degenerative cervical myelopathy (DCM), glioblastoma, substance abuse/addiction, and chemotherapy-induced peripheral neuropathy. MediciNova has a portfolio of patents which covers the use of MN-166 (ibudilast) to treat various diseases including ALS, progressive MS, and drug addiction.

About MediciNova

MediciNova, Inc. is a publicly-traded biopharmaceutical company founded upon developing novel, small-molecule therapeutics for the treatment of diseases with unmet medical needs with a primary commercial focus on the U.S. market. MediciNova's current strategy is to focus on MN-166 (ibudilast) for neurological disorders such as progressive multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), degenerative cervical myelopathy (DCM), substance dependence (e.g., alcohol use disorder, methamphetamine dependence, opioid dependence) and glioblastoma (GBM), and MN-001 (tipelukast) for fibrotic diseases such as nonalcoholic steatohepatitis (NASH) and idiopathic pulmonary fibrosis (IPF). MediciNova's pipeline also includes MN-221 (bedoradrine) and MN-029 (denibulin). For more information on MediciNova, Inc., please visit www.medicinova.com.

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, 2018 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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