MediciNova Announces Plans to Move Forward with a Phase 3 Trial of MN-166 (ibudilast) in ALS

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U.S. Food and Drug Administration has completed its review and determined that the study may proceed

LA JOLLA, Calif., April 15, 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 the U.S. Food and Drug Administration (FDA) has completed its review of the protocol and determined that MediciNova may proceed with a Phase 2b/3 clinical trial of MN-166 (ibudilast) in amyotrophic lateral sclerosis (ALS). If this potentially pivotal trial is successful, the Phase 2b/3 efficacy and safety data is intended to support a New Drug Application (NDA) for MN-166 (ibudilast) in ALS. The trial will be fully funded by MediciNova.

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased to have successfully completed the FDA review period and look forward to initiating patient enrollment shortly. The efficacy and safety data from this trial will potentially support an NDA and may lead to FDA approval of MN-166 for ALS. While we acknowledge this was an important milestone, and we have a clear path forward, this moment is of great importance to the ALS community. We give them our sincerest appreciation for their patience and optimism." Dr. Iwaki further commented, "Patients will be eligible to receive study drug from MediciNova after completing the required treatment period in this trial."

About the ALS Trial

Based on review and discussion of the Phase 1b/2a trial results with FDA, the design of the Phase 2b/3 clinical trial includes the following elements:

- Multi-center, two-arm, randomized, double-blind, placebo-controlled trial to evaluate MN-166 (ibudilast) vs. placebo in approximately 150 ALS patients in the U.S.;
- Patients will be randomized 1:1 to receive either 100 mg/day MN-166 (ibudilast) or placebo for 9 months;
- The primary endpoint is the mean change in functional activity at Month 9 as measured by the ALSFRS-R score (Amyotrophic Lateral Sclerosis Functional Rating Scale-revised), which is an approvable endpoint and is a widely accepted tool to measure the functional status of ALS patients;
- Secondary endpoints include mean change from baseline of muscle strength and quality of life, the utilization of and time to clinically indicated prescription for non-invasive ventilation, safety and tolerability.

Major inclusion criteria for trial eligibility will include ALS onset no more than 18 months before screening, at least one documented ALSFRS-R score between 3 and 6 months before screening, use of riluzole for at least 30 days before initiation of study drug, and total ALSFRS-R score of at least 35 at screening. Patients taking Radicava (edaravone) or Nuedexta (dextromethorphan/quinidine) may qualify for enrollment if these treatments are suspended 3 months prior to signing consent.

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 6,000 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 glioblastoma, substance abuse/addiction, and chemotherapy-induced 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), 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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