MediciNova Announces Plans to Develop MN-166 (ibudilast) for Severe Pneumonia and Acute Respiratory Distress Syndrome (ARDS)

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LA JOLLA, Calif., March 09, 2020 (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 it plans to initiate development of MN-166 (ibudilast) for severe pneumonia and acute respiratory distress syndrome (ARDS). MediciNova's decision to pursue development of this indication was based on positive results of a recent preclinical study in an animal model of ARDS (*Med Sci Monit, 2020; 26: e922281*). Results of this preclinical study showed that ibudilast treatment reversed histological changes observed in the ARDS mouse model including inflammation, hemorrhage, alveolar congestion, and alveolar wall edema. In this study, the pulmonary edema score was used to assess the degree of lung water accumulation. Importantly, pulmonary edema was significantly reduced by ibudilast treatment ($p<0.001$). Results of this study also showed that ibudilast significantly reduced the levels of inflammatory cytokines including TNF-alpha ($p<0.001$), IL-1beta ($p<0.001$), IL-6 ($p<0.001$), and MCP-1 ($p<0.001$) in a dose-dependent manner, indicating that ibudilast suppressed the inflammatory response. Results of this study also suggest that ibudilast protects against pulmonary injury by attenuating cell apoptosis in lung tissue.

Yuichi Iwaki, M.D. Ph.D., President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased to announce our initiation of development of MN-166 for severe pneumonia and ARDS. Severe pneumonia and ARDS are very serious conditions which are often caused by viral infections and often are fatal in hospitalized patients. Considering the global outbreak of influenza and coronavirus, it's very important to develop an efficient and safe treatment for these conditions. We believe that MN-166 has great potential for the treatment for severe pneumonia and ARDS patients based on its anti-inflammatory mechanism and strong results from the ARDS animal model study."

About Acute Respiratory Distress Syndrome

Acute respiratory distress syndrome (ARDS) is a serious lung condition that causes low blood oxygen. In ARDS, fluid builds up inside the tiny air sacs of the lungs, and surfactant breaks down. Surfactant is a foamy substance that keeps the lungs fully expanded so that a person can breathe. These changes prevent the lungs from filling properly with air and moving enough oxygen into the bloodstream and throughout the body. The lung tissue may scar and become stiff. ARDS may develop over a few days, or it can get worse very quickly. The first symptom of ARDS is usually shortness of breath. Other signs and symptoms of ARDS are low blood oxygen, rapid breathing, and clicking, bubbling, or rattling sounds in the lungs when breathing. Infections are the most common risk factors for ARDS. These infections may include the flu, coronavirus or other viruses, and sepsis. The rate of death in the hospital is approximately 40% for ARDS patients.

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. Our earlier human studies demonstrated significant reductions of serum MIF level after treatment with MN-166 (ibudilast). It also 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, 2019 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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