MediciNova Announces Plans to Initiate a Clinical Trial of MN-166 (ibudilast) for COVID-19 Acute Respiratory Distress Syndrome (ARDS)

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LA JOLLA, Calif., April 08, 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 will initiate a clinical trial of MN-166 (ibudilast) for acute respiratory distress syndrome (ARDS) caused by COVID-19 (Coronavirus Disease 2019).

The study will be conducted by Yale's Advanced Therapies Group, which is co-directed by Richard Bucala, M.D., Ph.D., Chief, Rheumatology, Allergy & Immunology at Yale School of Medicine and Rheumatologist-in-Chief at Yale New Haven Health. Dr. Bucala, is credited with the cloning of MIF (macrophage migration inhibitory factor) and its receptor and led prior efforts targeting MIF in autoimmunity and in cancer.

The lead Principal Investigator (PI) for this trial is Dr. Geoffrey Chupp, Professor of Medicine (Pulmonology), Director of the Yale Center for Asthma and Airway Disease and Director of the Pulmonary Function Laboratory at Yale-New Haven Hospital. The co-investigators include Dr. Maor Sauler, a physician scientist in Pulmonary and Critical Care Medicine who specializes in adult critical care including acute lung injury and sepsis, and Dr. Insoo Kang, Director, Allergy & Immunology, who are also members of the COVID-19 Advanced Therapeutic Group.

"We are very excited to partner with MediciNova to pursue this novel approach for the treatment of lethal inflammation in COVID-19 patients," commented Dr. Richard Bucala. "This study is especially gratifying because MN-166's inhibition of MIF activity was discovered in Yale Pharmacology by Elias Lolis, Ph.D. We believe MN-166 has the potential to reduce the mortality of COVID-19 by limiting the hyperinflammation and ARDS associated with severe cases."

Dr. Geoffrey Chupp commented, "We are very pleased to have the opportunity to study MN-166 in COVID-19-induced ARDS patients and look forward to initiating treatment. We currently have approximately 200 COVID-19 patients at Yale with 34 on ventilators. We are hopeful that MN-166 will help patients with the most severe cases of COVID-19."

Yuichi Iwaki, M.D. Ph.D., President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased to announce initiation of a clinical trial of MN-166 in ARDS caused by COVID-19. This study also will allow investigators to determine the optimal dose and route of administration in these very critical patients."

About Acute Respiratory Distress Syndrome

Acute respiratory distress syndrome (ARDS) is a frequently lethal lung condition caused by excessive inflammation for which there are no effective therapies beyond supportive care. Normally, the lung exchanges oxygen for carbon dioxide in small airway sacs called alveoli. In ARDS, there is extensive inflammation and tissue injury in the alveoli of the lungs, and loss of the surfactant, a substance necessary for keeping alveoli open. These changes prevent the lungs from filling properly with air and providing the body with enough oxygen, causing life-threatening difficulty breathing. 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, shallow, and/or rapid breathing. Infections are the most common cause of ARDS. These infections may include the flu, coronavirus, 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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