MediciNova Announces Opening of Investigational New Drug Application for MN-166 (ibudilast) for Prevention of Acute Respiratory Distress Syndrome in Patients with COVID-19

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LA JOLLA, Calif., July 01, 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 the Investigational New Drug Application (IND) for MN-166 (ibudilast) for prevention of Acute Respiratory Distress Syndrome (ARDS) has been accepted and is now open with the U.S. Food and Drug Administration (FDA). MediciNova was informed by the FDA that the proposed clinical investigation of MN-166 (ibudilast) for the prevention of ARDS in patients with COVID-19 may proceed.

Yuichi Iwaki, M.D., Ph.D., President and Chief Executive Officer of MediciNova, Inc., commented, “We are very pleased that this important regulatory step is completed, as we are now pursuing clinical development of MN-166 in patients with COVID-19 who are at risk for developing ARDS. We believe that MN-166 has potential to prevent deaths from COVID-19 by reducing hyperinflammation and cytokine storm. As we previously reported, treatment with MN-166 (ibudilast) reversed histological changes observed in the ARDS mouse model including inflammation, hemorrhage, alveolar congestion, and alveolar wall edema. MN-166 also significantly reduced serum inflammatory cytokines, significantly reduced pulmonary edema in lung tissue, and protected against pulmonary injury by reducing cell apoptosis in lung tissue. In addition to strong evidence from the ARDS mouse model, MN-166 has been identified as a hit compound with potential anti-SARS-CoV-2 effect and its long known anti-thrombotic effect may prevent or treat blood clots in COVID-19 patients, who commonly experience pulmonary embolism. Considering COVID-19’s high infection rate, there is an urgent need to develop an effective and safe treatment in patients at risk of developing ARDS."

About the Trial

Based on review and discussion with FDA, the design of the Phase 2 clinical trial includes the following elements:

- Randomized (1:1), double-blind, placebo-controlled, parallel group study in hospitalized COVID-19 patients at risk for developing ARDS and receiving standard-of-care including anticoagulation therapy.
- Subjects will be randomly assigned to receive up to 100 mg/day MN-166 or matching placebo for 7 days;
    - Patients will be followed up at Days 14 and 28;
    - The co-primary objectives include the proportion of subjects free of respiratory failure, subjects’ change in clinical status measured by NIAID scale, and plasma cytokine levels after 7 days of treatment;
    - Secondary objectives include safety, tolerability, and the proportion of subjects free of respiratory failure on Day 14.

Major inclusion criteria for trial eligibility will include confirmed SARS-CoV-2 infection, oxygen saturation (SpO_2) ≤92% on room air, chest imaging with abnormalities consistent with COVID-19 pneumonia, and has at least one risk factor that poses a higher risk for more severe illness from COVID-19.

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

MN-166 (ibudilast) has been marketed in Japan and Korea since 1989 to treat post-stroke complications and bronchial asthma. MN-166 (ibudilast) is a first-in-class, orally bioavailable, small molecule phosphodiesterases (PDE) 4 and 10 inhibitor and a macrophage migration inhibitory factor (MIF) inhibitor that suppresses pro-inflammatory cytokines and promotes neurotrophic factors. It attenuates activated glia cells, which play a major role in certain neurological conditions. Ibudilast's anti-neuroinflammatory and neuroprotective actions have been demonstrated in preclinical and clinical study results and provide the rationale for its therapeutic utility in substance use disorders, neurodegenerative diseases (e.g., ALS and progressive MS), and chronic neuropathic pain. MediciNova is developing MN-166 for various neurological conditions such as progressive MS, ALS and substance abuse/addiction.

About MediciNova

MediciNova, Inc. is a publicly traded biopharmaceutical company founded upon acquiring and 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) and substance dependence (e.g., alcohol use disorder, methamphetamine dependence, opioid dependence) 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) for the treatment of acute exacerbations of asthma and MN-029 (denibulin) for solid tumor cancers. MediciNova is engaged in strategic partnering and other potential funding discussions to support further development of its programs. 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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