MediciNova Announces Positive Top-Line Results from Phase 2 Clinical Trial of MN-166 (ibudilast) in Hospitalized COVID-19 Patients at Risk for Acute Respiratory Distress Syndrome

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LA JOLLA, Calif., June 08, 2022 (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 positive top-line results from MediciNova's Phase 2 clinical trial of MN-166 (ibudilast) in hospitalized COVID-19 patients at risk for developing acute respiratory distress syndrome (ARDS). MN-166 (ibudilast) demonstrated large improvements compared to placebo for all four clinical endpoints analyzed. The trial achieved statistical significance for one of the co-primary endpoints, the proportion of subjects free of respiratory failure. The trial also achieved statistical significance for the proportion of subjects discharged from the hospital.

The clinical trial enrolled 36 subjects and randomized 34 subjects including 17 subjects in the MN-166 (ibudilast) group and 17 subjects in the placebo group. Male and female participants (mean age = 60 years) were equally represented in MN-166 (ibudilast) and placebo treatment groups. The top-line results include analysis of two pre-defined co-primary endpoints and two additional endpoints.

- Co-primary endpoint of the proportion of subjects free from respiratory failure at Day 7: 71% of subjects in the MN-166 (ibudilast) group and 35% of subjects in the placebo group were free of respiratory failure at Day 7 (p=0.02).
- Co-primary endpoint of clinical status (i.e., improvement on NIAID scale) at Day 7: 71% of subjects in the MN-166 (ibudilast) group and 47% of subjects in the placebo group had improved clinical status at Day 7 (p=0.08).
- Proportion of subjects discharged from the hospital at Day 7: 65% of subjects in the MN-166 (ibudilast) group and 29% of subjects in the placebo group were discharged from the hospital at Day 7 (p=0.02).
- Proportion of subjects with worsening of clinical status at Day 7: 0% of subjects in the MN-166 (ibudilast) group and 24% of subjects in the placebo group had worsened clinical status at Day 7 (p=0.05).
- There were two deaths in the placebo group and no deaths in the MN-166 (ibudilast) group.
- There were no serious adverse events related to MN-166 (ibudilast).

Kazuko Matsuda, MD, PhD, MPH, Chief Medical Officer of MediciNova, Inc., commented, "We wish to express our sincere thanks to the investigators, their staff, and the study participants for their dedication and courage to conduct and volunteer for this trial. The vaccines had not rolled out when this study commenced and health professionals placed themselves at risk while treating severely ill patients with COVID-19 infections who were willing to participate in this study despite the uncertainty of their outcomes. We are pleased to report the positive top-line results from this study. We believe MN-166 has potential for efficacy in all patients with risk for ARDS and acute lung injury caused by COVID-19 or other infections or causes. There is a large unmet medical need for better treatments as the current rate of death in the hospital is approximately 40% for ARDS patients. We plan to discuss the results of this study with the FDA and get their feedback to determine next steps."

About the Clinical Trial

This study was a multi-center, randomized (1:1), double-blind, placebo-controlled, parallel-group study of MN-166 (ibudilast) in hospitalized patients with COVID-19 at risk for developing ARDS and receiving standard of care, including anticoagulation therapy. Major inclusion criteria for trial eligibility included confirmed SARS-CoV-2 infection, oxygen saturation (SpO2) ≤92% on room air, chest imaging with abnormalities consistent with COVID-19 pneumonia and had at least one risk factor that posed a higher risk for more severe illness from COVID-19. Eligible participants were randomly assigned to MN-166 (ibudilast) 100 mg/day or matching placebo treatment for 7 days. The co-primary objectives include the proportion of subjects free from respiratory failure and subjects' change in clinical status measured by the NIAID scale at Day 7. Assessments performed include clinical status, oxygen therapy use status, adverse events, and survival status.

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, and loss of the surfactant, a substance necessary for keeping the 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, and shallow and/or rapid breathing. Infections, including the flu, coronavirus, and other viruses, are the most common cause of ARDS. According to the ARDS Foundation, there are an estimated 190,000 ARDS cases per year in the U.S. The rate of death in the hospital is approximately 40% for ARDS patients.

About MN-166 (ibudilast)

MN-166 (ibudilast) is a small molecule compound that inhibits phosphodiesterase type-4 (PDE4) and inflammatory cytokines, including macrophage migration inhibitory factor (MIF). It is in late-stage clinical development for the treatment of neurodegenerative diseases such as ALS (amyotrophic lateral sclerosis), progressive MS (multiple sclerosis), and DCM (degenerative cervical myelopathy); and is also in development for glioblastoma,

CIPN (chemotherapy-induced peripheral neuropathy), and substance use disorder. In addition, MN-166 (ibudilast) was evaluated in patients that are at risk for developing acute respiratory distress syndrome (ARDS).

About MediciNova

MediciNova, Inc. is a clinical-stage biopharmaceutical company developing a broad late-stage pipeline of novel small molecule therapies for inflammatory, fibrotic, and neurodegenerative diseases. Based on two compounds, MN-166 (ibudilast) and MN-001 (tipelukast), with multiple mechanisms of action and strong safety profiles, MediciNova has 11 programs in clinical development. MediciNova's lead asset, MN-166 (ibudilast), is currently in Phase 3 for amyotrophic lateral sclerosis (ALS) and degenerative cervical myelopathy (DCM) and is Phase 3-ready for progressive multiple sclerosis (MS). MN-166 (ibudilast) is also being evaluated in Phase 2 trials in glioblastoma and substance dependence. MN-001 (tipelukast) was evaluated in a Phase 2 trial in idiopathic pulmonary fibrosis (IPF) and is in preparation for a second Phase 2 trial in non-alcoholic fatty liver disease (NAFLD). MediciNova has a strong track record of securing investigator-sponsored clinical trials funded through government grants.

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, 2021 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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