MediciNova Announces Health Canada Grants Authorization to Commence Multi-arm Phase 2/3 Clinical Trial to Evaluate MN-166 (ibudilast) in Long COVID

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LA JOLLA, Calif., Feb. 08, 2023 (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 Health Canada has completed its review of the clinical trial application and has granted authorization to commence a grant-funded, multi-center, randomized, clinical trial to evaluate MN-166 (ibudilast) and other therapies for the treatment of Long COVID, the lingering symptoms of COVID-19.

The trial, entitled **RE**covering from **C**OVID-19 **L**ingering Symptoms **A**daptive **I**ntegrative **M**edicine, or “RECLAIM,” is a collaboration between MediciNova and the University Health Network, the largest hospital-based research program in Canada. MediciNova will supply the study drug and will provide regulatory and safety follow-up support.

Kazuko Matsuda, M.D. Ph. D, M.P.H., Chief Medical Officer, MediciNova, Inc., commented, “Since COVID-19 became a global health threat, multiple vaccines and treatment options became available, yet not many treatment options have been evaluated in COVID-19 sequelae, so-called Long COVID. There is a large unmet medical need for patients with this disorder, which can have serious ramifications on quality of life, health care utilization and ability to return to work. We are very excited about the initiation of this multi-arm Phase 2/3 trial to evaluate MN-166 as a drug candidate for Long COVID.”

About the RECLAIM Trial

This is a Canada-wide Phase 2/3, prospective, adaptive, randomized, placebo-controlled platform trial to evaluate various interventions for patients with lingering symptoms of COVID-19 (“Long COVID”). Participants will be randomly assigned to 1 of 4 arms, MN-166 (ibudilast), pentoxifylline, or their respective matching placebo, including standard of care for 2 months, and will be followed for an additional 4 months. Approximately 800-1000 patients with Long COVID will be recruited at Canadian sites. The primary outcome measure is the mean change in the SF-36 (v.1) physical component score (PCS) from baseline to 2 months. As this is an adaptive design study, Intervention arms may be discontinued based on interim analysis results, and new interventions may be selected and included as part of the platform as the trial progresses.

About Long COVID

While most patients with COVID-19 recover completely within a few weeks, some people have symptoms that persist after the acute sickness has passed. "Long COVID", or the post-acute sequelae of SARS-CoV-2 (PASC), is a constellation of lingering symptoms of COVID-19 that are both broad and diverse. Fatigue, shortness of breath with exertion, cough, tachycardia, brain fog, insomnia/sleep disturbances, gastrointestinal disorders, skin rashes, anxiety, depression, and post-traumatic stress disorder are some of the persisting symptoms. It is estimated that 10% to 30% of patients may experience Long COVID after recovering, even if they weren’t seriously ill during the acute phase.

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 a second Phase 2 trial in non-alcoholic fatty liver disease (NAFLD) is ongoing. 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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