MediciNova Announces Completion of Enrollment in the Phase 2b Clinical Trial of MN 166 (ibudilast) in Alcohol Use Disorder

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LA JOLLA, Calif., Jan. 30, 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 the Phase 2b clinical trial evaluating MN-166 (ibudilast) for the treatment of alcohol use disorder (AUD) has completed enrollment.

This clinical trial was funded by the National Institute on Alcohol Abuse and Alcoholism (NIAAA). The NIAAA R01 research funding (R01AA026190) was awarded to Principal Investigator Dr. Lara Ray, PhD, ABPP, at the University of California, Los Angeles' (UCLA) Departments of Psychology, and Psychiatry and Biobehavioral Sciences Brain Research Institute. The clinical trial evaluated MN-166 (ibudilast) as a potential treatment to decrease alcohol consumption in treatment-seeking individuals diagnosed with AUD. MediciNova provided drug supply and regulatory support for the clinical trial.

Lara Ray, PhD, Principal Investigator of the study, commented, "We have completed enrollment and are conducting follow-up on the last of the participants. Recent studies of MN-166 (ibudilast) have shown it to be a safe and promising compound for the treatment of AUD and we are eager to begin the analysis."

Kazuko Matsuda, MD, PhD, MPH, Chief Medical Officer of MediciNova, Inc., commented, "We appreciate the continued grant support for this program by the NIH, Dr. Ray's team for their outstanding conduct of the trial, and all of the participants who contributed to the successful completion of enrollment. We are pleased that enrollment has completed and look forward to the reporting of topline results."

About the Clinical Trial
This study is a randomized, double-blind, placebo-controlled, outpatient clinical trial which enrolled 102 treatment-seeking men and women with moderate or severe AUD. Participants took MN-166 (ibudilast) 50 mg or placebo twice a day for 12 weeks and completed the NIAAA-developed web-based program *Take Control* during the study. The primary endpoint of the trial is to test whether MN-166 (ibudilast) will decrease percent heavy drinking days (defined as ≥5 drinks for men and ≥4 drinks for women), as compared to placebo, over the course of the 12-week trial. The secondary endpoints are to test the efficacy of MN-166 (ibudilast) on 1) the number of drinks consumed per day, 2) the number of drinks consumed per drinking day, 3) the percentage of days abstinent, 4) the percentage of subjects with no heavy drinking days, and 5) the percentage of subjects who are abstinent, as well as measures of alcohol craving and negative mood, over the course of the 12-week trial. Exploratory endpoints include evaluation of whether the effects of MN-166 (ibudilast) on the primary and secondary endpoints are moderated by depressive symptomatology and whether MN-166 (ibudilast) reduces neuroinflammation over the course of the 12-week trial.

About Alcohol Use Disorder
Alcohol use disorder (AUD) is a prevalent and disabling psychiatric disorder with limited treatment options. According to the National Institute on Alcohol Abuse and Alcoholism (NIAAA), an estimated 14.5 million people in the U.S. have AUD and less than 10% receive treatment for the disease. There is a high unmet medical need for better treatments for AUD.

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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