MediciNova Announces Initiation of a Phase 2 Trial of MN-001 (tipelukast) in NAFLD with Type 2 Diabetes Mellitus and Hypertriglyceridemia

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LA JOLLA, Calif., July 26, 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 the initiation of a Phase 2 clinical trial to evaluate MN-001 (tipelukast) for the treatment of patients with non-alcoholic fatty liver disease (NAFLD), type 2 diabetes mellitus (T2DM), and hypertriglyceridemia.

Kazuko Matsuda, MD, PhD, Chief Medical Officer of MediciNova, Inc., commented, "We are very pleased that this Phase 2 trial evaluating MN-001 has commenced. MN-001 appears to reduce serum lipid profiles in patients with a dual diagnosis of NAFLD and T2DM/prediabetes with dyslipidemia. The efficacy and safety data from this trial, if successful, could lead to a pivotal Phase 3 trial intended to support an NDA for MN-001 to treat dyslipidemia and reduce liver fat content in patients with NAFLD with T2DM/prediabetes."

About the NAFLD with Type 2 Diabetes Mellitus and Hypertriglyceridemia Trial

This is a Phase 2, multi-center, randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy and safety of MN-001 (tipelukast) in patients with NAFLD, T2DM and hypertriglyceridemia. The design of the Phase 2 clinical trial includes the following elements:

- Approximately 40 male and female patients, ages 21 to 75 years, in the U.S.
- Patients will be randomized 1:1 to receive either 500 mg/day of MN-001 (tipelukast) or placebo for 24 weeks.
- The co-primary endpoints are (1) change from baseline in liver fat content measured by MRI Proton Density Fat Fraction (MRI-PDFF) at Week 24, and (2) change from baseline in fasting serum triglycerides at Week 24. MRI-PDFF is a non-invasive, quantitative, and accurate measure of liver fat content commonly used in early phase trials to measure treatment response.
- Secondary endpoints include safety and tolerability and changes in lipid profile (HDL-C, LDL-C, and total cholesterol).

About NAFLD, Type 2 Diabetes Mellitus, and Hypertriglyceridemia

NAFLD is considered the hepatic manifestation of metabolic syndrome; studies have reported that 50% of patients with metabolic syndrome also have NAFLD. There is sufficient clinical and epidemiological evidence supporting the assertion that NAFLD is strongly associated with an increased prevalence and incidence of cardiovascular disease, T2DM, chronic kidney disease, and malignancy. The presence of dyslipidemia (hypercholesterolemia, hypertriglyceridemia, or both) is reported in 20 - 80% of NAFLD cases.

About MN-001 (tipelukast)

MN-001 (tipelukast) is a novel, orally bioavailable, small molecule compound thought to exert its effects through several mechanisms to produce its anti-inflammatory and anti-fibrotic activity in preclinical models, including leukotriene (LT) receptor antagonism, inhibition of phosphodiesterases (PDE) (mainly 3 and 4), and inhibition of 5-lipoxygenase (5-LO). The 5-LO/LT pathway has been postulated as a pathogenic factor in fibrosis development, and MN-001's inhibitory effect on 5-LO and the 5-LO/LT pathway is a novel approach to treat fibrosis. MN-001 has been shown to down-regulate expression of genes that promote fibrosis including LOXL2, Collagen Type 1 and TIMP-1. MN-001 has also been shown to down-regulate expression of genes that promote inflammation including CCR2 and MCP-1. In addition, MN-001 was found to inhibit triglyceride synthesis in hepatocytes by inhibiting arachidonic acid uptake.

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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