# MediciNova Announces Additional Positive Results Regarding the Effects of MN-001 (tipelukast) on Serum Lipid Panel in Type 2 Diabetes and NAFLD Patients Presented at IDF 2022 Congress, the Annual Meeting of the International Diabetes Federation

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LA JOLLA, Calif., Dec. 06, 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 that MediciNova's Chief Medical Officer, Kazuko Matsuda, MD PhD MPH, presented positive results from a subgroup analysis of the completed Phase 2 clinical trial which evaluated MN-001 (tipelukast) for the treatment of hypertriglyceridemia at the International Diabetes Federation (IDF) World Diabetes Congress 2022 held online December 5 - 8, 2022.

In the completed Phase 2 study, MN-001 (tipelukast) significantly reduced serum triglycerides in participants with non-alcoholic fatty liver disease (NAFLD) and hypertriglyceridemia (HTG). Subsequent in vitro results revealed that MN-001 (tipelukast) downregulated CD36 and upregulated ABCG1 mRNA expression, both of which are highly associated with Type 2 diabetes mellitus (T2DM). Hypothesizing that MN-001 (tipelukast) might be more effective at reducing serum triglycerides in participants with a dual diagnosis of NAFLD and Type 2 diabetes mellitus (T2DM), a subgroup analysis was conducted in participants with and without T2DM.

In the presentation entitled, "*Improvement of Serum Lipid Panel by Tipelukast (MN-001) in Type 2 Diabetes Mellitus and Non-alcoholic Fatty Liver Disease Patients*" (Abstract #LI2022-1192) the following results were announced:

- Compared to subjects without T2DM, the T2DM group showed a greater reduction in serum triglyceride levels at Week 8 (*50.8% reduction for with T2DM versus 17.8% reduction for without T2DM, p=0.098*).
- Mean HDL increase was significantly greater in subjects with T2DM than subjects without T2DM at Week 8 (*15.8% versus 1.0%, p<0.0002*).
- In comparison to subjects without T2DM, the T2DM group showed a greater reduction in serum LDL levels at Week 8 (*15.4% versus 6.7%*).

Kazuko Matsuda, M.D. Ph.D., M.P.H., Chief Medical Officer, MediciNova, Inc., commented, "We are very pleased to present this subgroup analysis of the results of our completed Phase 2 trial in individuals diagnosed with NAFLD and hypertriglyceridemia. Those participants with T2DM/prediabetes showed greater improvement in the serum lipid profile than participants without T2DM. These findings suggest that MN-001 is a potential treatment for patients with dyslipidemia and NAFLD due to T2DM. A trial to evaluate the efficacy and safety of MN-001 in patients with T2DM, NAFLD, and HTG is currently ongoing."

**About NAFLD, Type 2 Diabetes Mellitus (T2DM), 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**

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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