MediciNova Announces Topline Results from MN-001-NATG-202 Clinical Trial of MN-001 (Tipelukast)

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MN-001 showed statistically significant increases in HDL-C and HDL-P and significant early reduction in triglyceride, a reduction in body weight and a numerical improvement in liver fat

LA JOLLA, Calif., Sept. 28, 2026 (GLOBE NEWSWIRE) -- MediciNova, Inc., a biopharmaceutical company traded on the NASDAQ Global Market (NASDAQ: MNOV) and the Standard Market of the Tokyo Stock Exchange (Code Number: 4875), today announced the topline results from MN-001-NATG-202, a Phase 2 clinical trial evaluating MN-001 (tipelukast) for the treatment of hypertriglyceridemia and nonalcoholic fatty liver disease (NAFLD) associated with type 2 diabetes mellitus (T2DM). In the MN-001 group, reductions in serum triglycerides (TG), increases in serum high-density lipoprotein cholesterol (HDL-C) and HDL particle concentration (HDL-P), and a numerical trend toward improvement in liver fat and body weight were observed. MN-001 demonstrated a generally favorable safety and tolerability profile.

Study Overview

MN-001-NATG-202 was a randomized, double-blind, placebo-controlled study designed to evaluate the efficacy, safety, and tolerability of MN-001 in 40 patients with NAFLD and hypertriglyceridemia associated with T2DM. The treatment period was 24 weeks.

Key Results

- **Serum TG**: At Week 24, mean serum TG decreased from baseline by 45.8 mg/dL (21.78%) in the MN-001 group and by 14.4 mg/dL (6.97%) in the placebo group. Thus, the mean decrease was 31.4 mg/dL greater with MN-001 than with placebo (p=0.113). At Week 4, mean serum TG decreased from baseline by 54.7 mg/dL (26.05%) in the MN-001 group and by 23.8 mg/dL (11.54%) in the placebo group. The mean decrease was 30.96 mg/dL greater with MN-001 than with placebo, and this difference was statistically significant (p=0.015).
- **Liver fat**: At Week 24, the mean controlled attenuation parameter (CAP) score measured by FibroScan® decreased from baseline by 14.1 dB/m (4.24%) in the MN-001 group and by 4.3 dB/m (1.27%) in the placebo group. Thus, the mean decrease was 9.7 dB/m greater with MN-001 than with placebo; however, this difference was not statistically significant (p=0.2438).
- **HDL-C**: At Week 24, mean HDL-C increased by 3.3 mg/dL (8.39%) in the MN-001 group but decreased by 2.4 mg/dL (6.23%) in the placebo group. The difference between the MN-001 and placebo groups was 5.7 mg/dL and was statistically significant (p=0.0048).
- **HDL-P**: At Week 24, mean HDL-P increased by 3.62 µmol/L (11.80%) in the MN-001 group but decreased by 0.9 µmol/L (3.00%) in the placebo group. The difference between the MN-001 and placebo groups was 4.52 µmol/L and was statistically significant (p=0.018).
- **Body weight**: At the end of the study, mean body weight decreased by 4.91 lb (2.28%) in the MN-001 group and by 0.55 lb (0.25%) in the placebo group. Thus, the mean decrease in body weight was 4.36 lb greater with MN-001 than with placebo (p=0.082).

Safety and Tolerability

MN-001 was generally safe and well tolerated. Treatment-related adverse events were mild to moderate in severity, and no drug related serious adverse events (SAEs) were reported in the study.

Clinical Significance of the Results

The study demonstrated a statistically significant reduction in serum TG at Week 4 with MN-001 than with placebo. At Week 24, the MN-001 group continued to show a numerical reduction from baseline value, although the difference between the MN-001 and placebo groups were not statistically significant. Statistically significant increases in HDL-C and HDL-P were also observed with MN-001 group while liver fat and body weight showed trends toward improvement. Collectively, these exploratory findings suggest that MN-001 may have beneficial effects across in several metabolic parameters including lipid metabolism, body weight, and liver fat.

The changes in TG, HDL-C, and HDL-P were also consistent with findings from preclinical in-vitro mechanism of action studies

and previous MN-001-NATG-201 clinical trial. Together with the clinical findings, these results provide a basis for further evaluation of MN-001 in metabolic and cardiovascular diseases.

Next Steps

This was a proof of concept, exploratory study involving 40 patients. Preliminary review of the topline data indicates that efficacy should be evaluated in a larger study. We will continue detailed analyses of the study data and assess the next stage of clinical development, including the appropriate patient population, endpoints, and sample size.

About MN-001

MN-001 (tipelukast) is a novel, orally bioavailable, small-molecule compound thought to exert its effects through several mechanisms to produce anti-inflammatory and antifibrotic activity in preclinical models, including leukotriene (LT) receptor antagonism, inhibition of phosphodiesterase (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 treating 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. It also inhibits triglyceride synthesis in hepatocytes by inhibiting arachidonic acid uptake. Recent research suggested that MN-002, the major metabolite of MN-001, significantly enhanced cholesterol efflux in macrophages by upregulating key transport proteins ABCA1 and ABCG1.

About Type 2 Diabetes Mellitus (T2DM), Dyslipidemia, and Nonalcoholic Fatty Liver Disease (NAFLD)

Type 2 diabetes mellitus (T2DM) is a metabolic disorder characterized by insulin resistance, which plays a central role in the development of dyslipidemia—abnormal levels of lipids in the blood. Hypertriglyceridemia (elevated triglycerides) is commonly observed in individuals with T2DM. It results from increased hepatic lipid synthesis and impaired clearance of triglyceride-rich lipoproteins. Hypercholesterolemia, particularly elevated LDL cholesterol and reduced HDL cholesterol, is also frequently seen and contributes to a higher risk of atherosclerosis. Dyslipidemia not only worsens glycemic control but also increases the risk of cardiovascular complications and liver-related conditions such as nonalcoholic fatty liver disease (NAFLD). NAFLD is considered a hepatic complication of insulin resistance and is frequently associated with T2DM and dyslipidemia.

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), each 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 Long COVID 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 nonalcoholic fatty liver disease (NAFLD) is ongoing. MediciNova has a strong track record of securing investigator-sponsored clinical trials funded through government grants.

Forward-Looking Statements

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 and MN-001. 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 and MN-001, 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, 2025 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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