MediciNova Announces Completion of Last Patient Last Visit in the MN-001-NATG-202 Clinical Trial of MN-001 (Tipelukast)

May 26, 2026

LA JOLLA, Calif., May 26, 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 completion of last patient last visit (LPLV) in its Phase 2 clinical trial, MN-001-NATG-202, evaluating MN-001 (tipelukast) for the treatment of hypertriglyceridemia and nonalcoholic fatty liver disease (NAFLD) associated with type 2 diabetes mellitus (T2DM).

The MN-001-NATG-202 study is a multicenter, randomized, double-blind, placebo-controlled trial evaluating MN-001 (tipelukast). Patients were 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, as measured by controlled attenuation parameter (CAP) score, at Week 24, and (2) change from baseline in fasting serum triglycerides at Week 24. Secondary endpoints include safety, tolerability, and changes in lipid profile (HDL-C, LDL-C, and total cholesterol). Top-line data are expected in the third quarter of 2026.

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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Source: MediciNova, Inc.