MediciNova Receives a Notice of Intention to Grant for a New Patent Covering MN-001 and MN-002 for the Treatment of Advanced NASH in Europe

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LA JOLLA, Calif., Aug. 14, 2023 (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 it has received a Notice of Intention to Grant from the European Patent Office for a pending patent application which covers MN-001 (tipelukast) and MN-002 (a major metabolite of MN-001) for the treatment of advanced nonalcoholic steatohepatitis (NASH).

Once issued, the patent maturing from this allowed patent application is expected to expire no earlier than May 2035. The allowed claims cover MN-001 (tipelukast) or MN-002 for the treatment of a patient diagnosed with advanced NASH. The allowed claims also cover the treatment of advanced NASH patients that exhibit spider angiomata, ascites, splenomegaly, hard liver border, palmar erythema, asterixis, portal hypertension, hepatic scarring, cirrhosis, or hepatocellular carcinoma (HCC). In addition, the allowed claims cover MN-001 (tipelukast) or MN-002 for reducing hepatic fibrosis and hepatic scarring in a patient with advanced NASH. The allowed claims cover oral administration, including tablets and capsules, as well as liquid dosage forms. The allowed claims cover a wide range of doses of MN-001 (tipelukast) or MN-002 and a range of different dosing frequencies.

Kazuko Matsuda, M.D. Ph.D, MPH., Chief Medical Officer, MediciNova, Inc., commented, “We are very pleased to receive notice that this new patent will be granted as we believe it could increase the potential value of MN-001. We previously reported positive results from a Phase 2 clinical trial of MN-001 that enrolled NASH and NAFLD patients with hypertriglyceridemia. The U.S. FDA has granted Fast Track designation for MN-001 for the treatment of NASH with fibrosis. The U.S. Patent and Trademark Office previously granted a patent which covers MN-001 and MN-002 for advanced NASH with fibrosis and similar patents were granted in Japan, Korea, and Canada.”

About MN-001 (tipelukast)

MN-001 (tipelukast) is a novel, orally administered, small molecule compound with multiple mechanisms of action which has been in clinical development for the treatment of chronic inflammatory and fibrotic diseases, among others, due to its anti-inflammatory and anti-fibrosis effects. Based on the finding that MN-001 (tipelukast) reduces triglycerides (TG) in the blood from our previous clinical trials, we conducted a Phase 2 clinical trial in patients with hypertriglyceridemia and NASH or NAFLD. Based on the findings from the in-vitro mechanistic study of MN-001 (tipelukast), a subgroup analysis of the Phase 2 clinical trial showed a stronger improvement in lipid profile in the NASH/NAFLD patients with a history of diabetes. Therefore, a new Phase 2 clinical trial was initiated to investigate the effect of MN-001 (tipelukast) in NAFLD patients with type 2 diabetes and hypertriglyceridemia.

The molecular mechanism of action of MN-001 (tipelukast) includes leukotriene receptor antagonism and inhibition of phosphodiesterase (mainly 3 and 4) and 5-lipoxygenase (5-LO) and these multiple mechanisms are believed to reduce inflammation and prevent fibrosis. We have also confirmed that MN-001 (tipelukast) suppresses fibrosis-promoting genes such as LOXL2, Collagen Type 1, and TIMP-1 and suppresses inflammation-promoting genes such as CCR2 and MCP-1 in a fibrosis disease model study. Although the direct mechanism of action of MN-001 (tipelukast) on TG reduction in blood has not yet been fully clarified, we are conducting joint research with Juntendo University with the aim of elucidating this mechanism of action.

In various animal models of fibrosis disease, MN-001 (tipelukast) has been shown to improve fibrosis on histopathological examination, and the FDA has granted Fast Track status to MN-001 (tipelukast) for the treatment of NASH with fibrosis. MN-001 (tipelukast) has also been granted Fast Track status and Orphan Drug designation for the treatment of idiopathic pulmonary fibrosis. In the past, we have conducted clinical trials for MN-001 (tipelukast) for the treatment of bronchial asthma and interstitial cystitis, and more than 600 patients have been treated with MN-001 (tipelukast) to date, confirming its good safety and tolerability profile.

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, 2022 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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