MediciNova Announces Phase 2 Trial of MN-001 (tipelukast) in NASH / NAFLD will be Terminated Early based on Significant Positive Results from Interim Analysis

April 1, 2018

LA JOLLA, Calif., April 01, 2018 (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 it will terminate the Phase 2 clinical trial of MN-001 (tipelukast) in NASH (non-alcoholic steatohepatitis) and NAFLD (non-alcoholic fatty liver disease) with hypertriglyceridemia early based on the significant positive results from an interim analysis.

MN-001 (tipelukast) significantly reduced mean serum triglycerides, a primary endpoint, from 260.1 mg/dL before treatment to 185.2 mg/dL after eight weeks of treatment (p=0.00006). There were no clinically significant safety or tolerability issues during the study. Having achieved the most important endpoint of the study, MediciNova will discontinue enrollment and stop the study in order to accelerate further development of MN-001.

Details of this interim analysis will be presented at the International Liver Congress 2018, the 53rd annual meeting of the European Association for the Study of the Liver (EASL), during the NAFLD: Therapy poster session on Friday, April 13, 2018 in Paris, France.

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We are thrilled with the results of this study, which showed a large reduction in triglycerides. Based on the results of this study, along with the triglyceride data we have from prior clinical studies of MN-001 in other indications, we believe that MN-001 has potential to benefit a wide range of patients with hypertriglyceridemia, not limited to those with NASH and NAFLD."

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About the Trial

The Phase 2a trial is a multi-center, proof-of-principle, open-label study designed to evaluate the efficacy, safety, and tolerability of MN-001 in subjects with non-alcoholic steatohepatitis (NASH) or non-alcoholic fatty liver disease (NAFLD) with hypertriglyceridemia. Eligible subjects consisted of males and females ranging in age from 21 to 65 years old, inclusive. To be eligible, subjects must have had a histologically confirmed diagnosis of NASH or imaging study confirmed NAFLD and an elevated serum triglyceride (>150 mg/dL) during the Screening Phase.

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 considered to be 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, histopathological data shows that MN-001 reduces fibrosis in multiple animal models.

About MediciNova

MediciNova, Inc. is a publicly-traded biopharmaceutical company founded upon acquiring and developing novel, small-molecule therapeutics for the treatment of diseases with unmet medical needs with a primary commercial focus on the U.S. market. MediciNova's current strategy is to focus on MN-166 (ibudilast) for neurological disorders such as progressive multiple sclerosis (progressive MS), amyotrophic lateral sclerosis (ALS) and substance dependence (e.g., alcohol use disorder, methamphetamine dependence, opioid dependence) and MN-001 (tipelukast) for fibrotic diseases such as nonalcoholic steatohepatitis (NASH) and idiopathic pulmonary fibrosis (IPF). MediciNova's pipeline also includes MN-221 (bedoradrine) for the treatment of acute exacerbations of asthma and MN-029 (denibulin) for solid tumor cancers. MediciNova is engaged in strategic partnering and other potential funding discussions to support further development of its programs. For more information on MediciNova, Inc., please visit www.medicinova.com.

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-221, MN-001, 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-221, MN-001, 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, 2017 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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