



MediciNova Announces MN-001 (tipelukast) NASH/NAFLD Phase 2 Trial Interim Results Selected for Presentation at the International Liver Congress 2018 in Paris, France

January 28, 2018

LA JOLLA, Calif., Jan. 28, 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 an abstract regarding an interim analysis from the ongoing Phase 2 clinical trial of MN-001 (tipelukast) in NASH/NAFLD patients has been accepted for poster presentation at the International Liver Congress 2018, the 53rd annual meeting of the European Association for the Study of the Liver (EASL), to be held April 11-15, 2018 in Paris, France.

Presentation details are as follows:

Title: The anti-fibrotic agent, tipelukast (MN-001) reduces serum triglyceride significantly in non-alcoholic steatohepatitis and non-alcoholic fatty liver disease patients with hypertriglyceridemia after 4 weeks of treatment, an interim analysis of ongoing clinical trial, MN-001-NATG-201

Session Date and Time: Friday, April 13, 2018 at 9:00 a.m. - 5:00 p.m. (local time)

Session: Poster Session: NAFLD: Therapy

Location: Paris expo Porte de Versailles - Pavillon 7, 1 Place de la Porte de Versailles, Paris, France

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 will consist of males and females ranging in age from 21 to 65 years old, inclusive. To be eligible, subjects must have a histologically confirmed diagnosis of NASH or imaging study confirmed NAFLD and an elevated serum triglyceride (>150 mg/dL) during the Screening Phase. Qualifying subjects will be given MN-001 250 mg orally administered once a day for the first 4 weeks and will be given MN-001 250 mg twice a day for an additional 8 weeks. Overall, the study timeline consists of a Screening Phase (up to 4 months) followed by a Treatment Phase (12 weeks), and a Follow-up visit (within 1 week after the last dose).

The primary efficacy endpoints of the study are to evaluate the effect of MN-001 on 1) triglyceride levels in NASH or NAFLD subjects with hypertriglyceridemia, and 2) cholesterol efflux capacity in NASH or NAFLD subjects with hypertriglyceridemia. Secondary endpoints include safety and tolerability of MN-001, PK profile of MN-001/MN-002 (by-product of MN-001), effects of MN-001 on HDL-C, LDL-C, and total cholesterol level, and effects of MN-001/002 on liver enzymes and percent fat in liver at Week 12.

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 MS, 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, 2016 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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