MediciNova Announces FDA Approval of the Second Phase 2 Protocol for MN-001 in NASH Which Targets NASH Patients With Hypertriglyceridemia

July 27, 2015

LA JOLLA, Calif., July 27, 2015 (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 FDA (U.S. Food and Drug Administration) has approved a second protocol for a clinical trial evaluating MN-001 (tipelukast) for a NASH indication. This study targets NASH patients with hypertriglyceridemia to evaluate the ability of MN-001 to improve cardiovascular risk by assessing cholesterol-efflux capacity and serum triglyceride levels as well as reduction of percent fat in the liver, as assessed by MRI.

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased to have successfully completed the FDA review period and look forward to initiating patient enrollment shortly. The safety and efficacy data from this trial will be important to our overall development efforts targeting NASH and should be complementary to efforts underway. In previous clinical trials and preclinical studies, serum triglyceride levels were reduced in MN-001-treated groups. It is well known that NASH patients often have elevated serum lipid levels, one of the factors that contribute to cardiovascular disease. Recent studies have confirmed that cardiovascular disease is the single most important cause of mortality in this patient population. Importantly, MN-001's anti-fibrotic properties combined with its potential to reduce triglyceride levels in NASH patients offers a novel approach to the treatment of NASH."

About the Study Design

The Phase 2 trial is a single-center, proof-of-principle, open-label study designed to evaluate the efficacy, safety, and tolerability of MN-001 in subjects with nonalcoholic steatohepatitis (NASH) and 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 within 6 months prior to the baseline visit and an elevated serum triglyceride (> 150 mg/dL) during the Screening Phase. Approximately twenty (20) 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 subjects with hypertriglyceridemia, and 2) Cholesterol Efflux Capacity in NASH 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 assessed using MRI at Week 12.

Earlier this year, the FDA granted Fast-Track designation to MN-001 for the treatment of NASH with fibrosis. Fast Track is a process designed to facilitate the development and expedite the review of drugs that are intended to treat serious or life-threatening diseases and demonstrate the potential to address unmet medical needs for such diseases. An important feature of the FDA's Fast Track program is that it emphasizes frequent communication between the FDA and the sponsor throughout the entire drug development and review process to improve the efficiency of product development. Accordingly, Fast Track status can potentially lead to a shortened timeline to ultimate drug approval.

About Nonalcoholic Steatohepatitis

Nonalcoholic steatohepatitis (NASH) is a condition in which there is fat in the liver along with inflammation and damage to liver cells. NASH is a common liver disease that resembles alcoholic liver disease but occurs in people who drink little or no alcohol. According to the U.S. National Digestive Diseases Information Clearinghouse (NDDIC), NASH prevalence in the U.S. is 2-5%, and an additional 10-20% of Americans have "fatty liver." The underlying cause of NASH is unclear, but it most often occurs in people who are middle-aged and overweight or obese. Many patients with NASH have elevated serum lipids, diabetes or pre-diabetes. Progression of NASH can lead to liver cirrhosis. Liver transplantation is the only treatment for advanced cirrhosis with liver failure. At this time, there is no treatment for NASH.

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.

Previously, MediciNova evaluated MN-001 for its potential clinical efficacy in asthma and had positive Phase 2 results. MN-001 has been exposed to more than 600 subjects and is considered generally safe and well-tolerated. Importantly, in these studies, reduction of serum triglyceride was observed for those treated with MN-001 in healthy volunteers and target populations.

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 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.*, methamphetamine dependence and 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, 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, 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, 2014 and its subsequent periodic reports on Forms 10-Q and 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.

CONTACT: INVESTOR CONTACT:
Geoff O'Brien
Vice President
MediciNova, Inc.
info@medicinova.com

MediciNova, Inc. Logo

MediciNova, Inc.