FDA Grants Fast Track Designation for MediciNova's MN-001 (tipelukast) for the Treatment of NASH with Fibrosis

April 16, 2015

LA JOLLA, Calif., April 16, 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 it has received Fast Track designation from the U.S. Food and Drug Administration (FDA) for MN-001 (tipelukast) for the treatment of patients with nonalcoholic steatohepatitis (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.

In January 2015, MediciNova announced an open Investigational New Drug (IND) application for MN-001 in NASH. Importantly, due to safety data from previous clinical studies of MN-001, FDA has agreed that MediciNova may proceed with a Phase 2 study as the first clinical study of MN-001 in NASH.

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased that MN-001 has received Fast Track designation and believe this validates its potential to address unmet medical needs in this life-threatening disease. We look forward to providing further updates as our development progresses."

About Fast Track Designation

According to the FDA, in order to be granted Fast Track designation, a drug must (1) be intended for the treatment of a serious or life-threatening disease or condition; and (2) demonstrate the potential to address unmet medical needs for the disease or condition.

A drug that receives Fast Track designation may be eligible for:

- More frequent meetings with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval;
- Accelerated Approval, i.e., approval based on an effect on a surrogate, or substitute endpoint reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality;
- Priority Review, with an FDA goal for completing review within six months of submission; and
- Rolling Review, which means that a sponsor can submit completed sections of its New Drug Application (NDA) for review by the FDA, rather than waiting until every section of the application is completed before the entire application can be reviewed.

About NASH (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 persons 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.

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, 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, 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.