MediciNova Announces Update on Development Plans for MN-001 in IPF

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LA JOLLA, Calif., July 21, 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 it is currently in late-stage discussions with investigators at Penn State University (principal investigator Dr. Rebecca Bascom) to conduct a Phase 2 study of MN-001 (tipelukast) for the treatment of moderate to severe IPF (idiopathic pulmonary fibrosis).

The Phase 2 trial is a randomized, placebo-controlled, double blind 6-month study followed by an open-label extension phase to evaluate the efficacy, safety, and tolerability of MN-001 in subjects with moderate to severe IPF. Approximately fifteen qualifying subjects will be randomly assigned in a 2:1 ratio to MN-001 750 mg or matching placebo orally administered twice a day for 26 weeks (double-blind treatment phase). After completion of the double-blind treatment phase, subjects will participate in the open-label extension (OLE) phase for an additional 6 months. Subjects who were in the placebo group will be administered MN-001 750 mg twice a day for remainder of the OLE Phase. Subjects randomized to the MN-001 group will continue on MN-001 for additional 6 months. A follow-up visit will occur within 4 weeks after last dose.

The primary efficacy endpoints of the study are to evaluate the effect of MN-001 on 1) change from baseline of forced vital capacity (FVC) and FVC% predicted up to 26 weeks, and 2) the semiannual rate of decline of disease activity based on forced vital capacity (FVC). Secondary endpoints include safety and tolerability, semiannual rate of decline on disease activity based on the 6-minute walk test (6MWT), change from baseline on disease activity based on Modified Medical Research Council Dyspnea Score (MMRC), change from baseline on quality of life (QOL) measured by A Tool to Assess Quality of Life in Idiopathic Pulmonary Fibrosis (ATAQ-IPF), frequency of worsening IPF, and time to first worsening of IPF.

FDA (U.S. Food and Drug Administration) has already approved the protocol for this clinical trial of MN-001 (tipelukast) for the treatment of moderate to severe IPF (idiopathic pulmonary fibrosis). Importantly, due to safety data from previous clinical studies of MN-001, FDA agreed that MediciNova may proceed with a Phase 2 study as the first clinical trial of MN-001 in IPF. The IPF protocol was filed under MediciNova's open IND (Investigational New Drug Application) in FDA's Division of Pulmonary, Allergy, and Rheumatology Products (DPARP). FDA has granted orphan-drug designation to MN-001 for the treatment of IPF, which will provide MediciNova with seven years of marketing exclusivity if MN-001 is approved for IPF.

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased that discussions are moving forward as planned with our potential study investigators. The study design for this trial includes severe IPF patients, which we believe have never been included in any other IPF clinical studies."

About Idiopathic Pulmonary Fibrosis

Pulmonary fibrosis (PF) is a progressive disease characterized by scarring of the lungs that thickens the lining, causing an irreversible loss of the tissue's ability to transport oxygen. The causes of PF vary and can be due to anti-cancer drug therapy or exposure to chemicals. Idiopathic pulmonary fibrosis (IPF) is one type of PF without a clear cause. According to the Coalition for Pulmonary Fibrosis, IPF affects approximately 128,000 individuals in the U.S., with about 48,000 new cases diagnosed annually. The prognosis for IPF is poor and about two-thirds of IPF patients die within five years of diagnosis.

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 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.

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