MediciNova Announces FDA Granted Orphan Drug Designation to MN-001 (tipelukast) for Idiopathic Pulmonary Fibrosis (IPF)

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LA JOLLA, Calif., Oct. 22, 2014 (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 the U.S. Food and Drug Administration (FDA) has granted orphan-drug designation to MN-001 (tipelukast) for treatment of idiopathic pulmonary fibrosis (IPF). Orphan-drug designation will provide MediciNova with seven years of marketing exclusivity for MN-001 (tipelukast) for the treatment of IPF if it is approved for this indication.

MediciNova previously opened an Investigational New Drug (IND) application with the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) for MN-001 (tipelukast).

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased to receive this orphan-drug designation, which is an important part of our development strategy for MN-001 in IPF. As we already have an open IND, we plan to finalize a protocol and submit it to FDA in order to conduct a Phase 2 clinical trial of MN-001 in IPF."

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 which exerts its effects through several mechanisms to produce its anti-fibrotic and anti-inflammatory 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 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 nonalcoholic steatohepatitis (NASH) and idiopathic pulmonary fibrosis (IPF) and other fibrotic disease. 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, 2013 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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