MediciNova Announces Results of Phase 2 Clinical Trial of MN-166 (ibudilast) in Methamphetamine Dependence

March 29, 2018

LA JOLLA, Calif., March 29, 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 the Phase 2 clinical trial of MN-166 (ibudilast) in methamphetamine dependence, which was recently completed by investigators at UCLA, did not meet the primary endpoint of methamphetamine abstinence confirmed via urine drug screens during the final two weeks of treatment (weeks 11 and 12). MN-166 (ibudilast) demonstrated a favorable safety and tolerability profile. There was not an increased rate of serious or severe adverse events in the MN-166 (ibudilast) group compared to the placebo group. There were no infections, no cancers, no cardiovascular events (i.e. no heart attacks or strokes), and no deaths related to MN-166 (ibudilast) treatment. The most common treatment-related adverse events during the study were gastrointestinal adverse events, which occurred with a higher frequency in the MN-166 (ibudilast) group.

Dr. Keith Heinzerling, MD, principal investigator of this study, commented, “It is disappointing that the study could not achieve the primary endpoint with this study design and setting.”

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented “We will conduct further analyses of the data with UCLA researchers, which will help us to better understand how to optimize study design and setting for any future clinical trials in substance dependence. We will discuss the results with NIH/NIDA who provided the funding for this trial, the opioid dependence trials and the alcohol dependence trial. We plan to meet with FDA after we have data from the ongoing study of MN-166 in methamphetamine use disorder at Oregon Health & Science University.”

About the Methamphetamine Dependence Clinical Trial:

This study was a randomized, double-blind, placebo-controlled, outpatient Phase 2 study of MN-166 (ibudilast) in treatment-seeking individuals with methamphetamine dependence, stratified by HIV serostatus, at a UCLA research clinic. Eligible participants were randomly assigned to MN-166 (ibudilast) 100 mg/day or placebo treatment for 12 weeks, with twice-weekly clinic visits for counseling, urine drug tests, and safety/medication adherence monitoring. The study was designed to detect a statistically significant benefit of MN-166 (ibudilast) over placebo on the primary study outcome of methamphetamine abstinence during the final two weeks of treatment.

About MN-166 (ibudilast)

MN-166 (ibudilast) has been marketed in Japan and Korea since 1989 to treat post-stroke complications and bronchial asthma. MediciNova is developing MN-166 for progressive multiple sclerosis (MS) and other neurological conditions such as ALS and substance abuse/addiction. MN-166 (ibudilast) is a first-in-class, orally bioavailable, small molecule phosphodiesterase (PDE) -4 and -10 inhibitor and a macrophage migration inhibitory factor (MIF) inhibitor that suppresses pro-inflammatory cytokines and promotes neurotrophic factors. It attenuates activated glia cells, which play a major role in certain neurological conditions. Ibudilast's anti-neuroinflammatory and neuroprotective actions have been demonstrated in preclinical and clinical study results and provide the rationale for its therapeutic utility in neurodegenerative diseases (e.g., progressive MS and ALS), substance abuse/addiction and chronic neuropathic pain. MediciNova has a portfolio of patents which cover the use of MN-166 (ibudilast) to treat various diseases including progressive MS, ALS, and drug addiction.

About MediciNova

MediciNova, Inc. is a publicly-traded biopharmaceutical company founded on acquiring and developing novel, small-molecule therapeutics for the treatment of diseases with high 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., opioid dependence, methamphetamine 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-001, MN-221 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-001, MN-221 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, 2017 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.

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

MediciNova, Inc.