MediciNova Announces Positive Findings from Completed Trial of MN-166 (ibudilast) in Methamphetamine Dependence Presented at the 50th Winter Conference on Brain Research

February 6, 2017

Leading addiction researchers discuss MN-166 in symposium on novel pharmacotherapies to treat substance use disorders

LA JOLLA, Calif., Feb. 06, 2017 (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 the presentation of results from a completed Phase 1b trial of MN-166 (ibudilast) in methamphetamine dependence at a symposium titled “Neuroimmune Modulation in Addiction: Preclinical and Clinical Findings” at the 50 th Winter Conference on Brain Research held from January 28 to February 2, 2017 in Big Sky, Montana.

Keith Heinzerling, M.D., M.P.H., Associate Professor, Department of Family Medicine and Medical Director of the UCLA Center for Behavioral and Addiction Medicine, and Marisa Briones, Ph.D., Postdoctoral Research Fellow, presented results for the completed Phase 1b trial which evaluated MN-166 (ibudilast) in patients with methamphetamine dependence.

Major highlights from the presentation, “Clinical Development of Ibudilast for Methamphetamine Use Disorder,” include the following:

- Ibudilast increased levels of the biomarker brain-derived neurotrophic factor (BDNF), a growth factor which helps to support the survival of existing neurons and encourages the growth of new neurons and synapses, when compared to placebo;
- Ibudilast decreased levels of the biomarker tumor necrosis factor (TNF_{α}), a pro-inflammatory cytokine, when compared to placebo (p=0.027);
- Ibudilast decreased levels of the biomarker vascular cell adhesion molecule (VCAM1), which mediates leukocyte-endothelial cell adhesion and signal transduction and may play a role in the development of neurodegenerative disorders, when compared to placebo (p=0.035);
- Ibudilast was safe and well tolerated during the methamphetamine infusions;
- Ibudilast is currently being investigated in a Phase 2 study to determine its ability to help methamphetamine users reduce or stop use altogether.

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased with ibudilast’s encouraging results reported in this study, specifically the data which demonstrates ibudilast’s neuroprotective and anti-neuroinflammatory effects in methamphetamine-dependent subjects. Moreover, these results validate MN-166’s neuroprotective and anti-inflammatory properties by evaluation of biomarkers for the first time in a clinical trial. Based on these findings, along with the positive safety and tolerability results, we look forward to advancing our program to further evaluate ibudilast’s potential utility in the treatment of methamphetamine dependence. Congratulations to the UCLA researchers on their unwavering efforts to evaluate MN-166 for this devastating disorder.”

About the Methamphetamine Dependence Clinical Trial

This study was a randomized, double-blind, placebo-controlled within-subject Phase 1b study of MN-166 (ibudilast) in methamphetamine-dependent, non-treatment seeking abusers. The study duration was approximately 6 weeks per subject. Participants were randomized to one of 2 medication sequences: 1) placebo - 20 mg ibudilast – 50 mg ibudilast twice/day or 2) 20 mg ibudilast - 50 mg ibudilast - placebo twice/day. Methamphetamine infusions (0 mg, 15 mg, 30 mg) were given while subjects were taking ibudilast or placebo and were followed by cardiovascular assessments, subjective effects ratings, and pharmacokinetic (PK) assessments.

The ongoing methamphetamine dependence study is a randomized, placebo-controlled, double-blind, outpatient Phase 2 study of MN-166 (ibudilast) which will enroll up to 140 treatment-seeking methamphetamine dependent subjects. Eligible participants are randomized, stratified by HIV serostatus, to ibudilast 50 mg twice a day or placebo treatment for 12 weeks, with twice weekly clinic visits for counseling, urine drug tests, and safety/medication adherence monitoring. The study is designed to detect a statistically significant benefit of MN-166 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 MS and other neurological conditions such as ALS and drug use disorders. 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 amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig’s disease), substance abuse/addiction and chronic neuropathic pain.

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, 2015 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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