MediciNova Announces Collaboration with the U.S. Department of Veterans Affairs and Oregon Health & Science University to Evaluate MN-166 (ibudilast) in Methamphetamine Use Disorder

November 9, 2017

LA JOLLA, Calif., Nov. 09, 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 that it plans initiate a biomarker study for evaluating MN-166 (ibudilast) in methamphetamine (MA) use disorder.

The clinical trial is a collaborative effort between MediciNova, Inc., Dr. William Hoffman, Associate Professor of Psychiatry and Behavioral Neuroscience at Oregon Health & Science University (OHSU), Staff Psychiatrist, Mental Health and Clinical Neurosciences Division at the Portland VA Medical Center, and Investigator in the Methamphetamine Abuse Research Center at OHSU, and Dr. Aaron Janowsky, Professor of Psychiatry and Behavioral Neuroscience, OHSU, Director, Methamphetamine Abuse Research Center, and Research Career Scientist at the Portland VA Medical Center in Portland, Oregon.

The proposed clinical trial will evaluate MN-166 (ibudilast) as a potential treatment for individuals diagnosed with MA use disorder with or without post-traumatic stress disorder (PTSD). This study has already completed FDA review and will be initiated by Dr. William Hoffman at Portland VA Medical Center and Oregon Health & Science University.

Dr. Yuichi Iwaki, President and CEO of MediciNova, Inc., commented, “We are excited to collaborate with Dr. Hoffman and Dr. Janowsky to explore the potential for MN-166 as a pharmacotherapy for methamphetamine use disorder. There is a large unmet medical need for patients with methamphetamine use disorder as there are no pharmaceutical treatments approved for this indication.”

Dr. William Hoffman, the Principal Investigator for this project, commented, “We are pleased to partner with MediciNova to evaluate MN-166 in the treatment of methamphetamine use disorder. Methamphetamine induces neuroinflammation in animal models and in humans, and recent studies have shown MN-166 to have positive results in methamphetamine craving and favorable toxicology.”

About the Trial

This is a double-blind, randomized, single-center, outpatient pilot study to evaluate MN-166’s (ibudilast) ability to decrease neuroinflammation and alter brain function in recently abstinent MA users (N=28). The study endpoints are 1) to determine the relationship between positron emission tomography (PET) /magnetic resonance spectroscopy (MRS) markers of neuroinflammation and ventral striatal responses to reward as assessed by the Monetary Incentive Delay Task (MID) with functional magnetic resonance imaging (fMRI) and mesocorticolimbic resting-state functional connectivity (RSFC) with resting-state fMRI; 2) to determine whether a 4-week treatment of ibudilast reduces neuroinflammation and alters brain function compared to placebo; and, 3) to determine if changes in neuroinflammation track with changes in mesocorticolimbic RSFC and in ventral striatal responses to reward. Studies have shown that neuroinflammation plays a role in abnormal brain function and MA induces neuroinflammation. Eligible subjects will receive 50 mg of MN-166 (ibudilast) or placebo twice a day for 4 weeks, with a Week 1 visit to evaluate safety and study medication adherence and a visit at Day 30 for assessments including laboratory tests, safety/medication adherence, and behavioral and cognitive questionnaires. Brain imaging assessments will be conducted on Day 0 (baseline) and Day 30. This study is supported by the U.S. Department of Veterans Affairs. MediciNova plans to provide regulatory, scientific and analytical support, as well as study drug and placebo supply.

About the Methamphetamine Abuse Research Center at OHSU and the Portland VA Medical Center

The Methamphetamine Abuse Research Center (MARC) at OHSU and the Portland VA Medical Center is a NIDA center that approaches drug research at all levels including brain, body, cognition, and genetics. These two institutions work in collaboration to advance the treatment of illnesses, especially co-existing conditions such as MA use disorder and PTSD in the military veteran population.

About Methamphetamine Use Disorder

According to the Substance Abuse and Mental Health Services Administration’s (SAMHSA) 2016 National Survey on Drug Use and Health, there are approximately 684,000 people aged 12 or older with methamphetamine use disorder (includes those with dependence or abuse) in the U.S. According to the Rand Corporation, the estimate of the economic burden in the U.S. of methamphetamine use, based on the most recent year for which data are available, is approximately $23.4 billion. Currently, there is no pharmaceutical treatment approved for methamphetamine dependence. Among veterans with substance use disorders, those with MA use disorder have additional behavioral, health care utilization, and psychiatric characteristics (US Department of Veterans Affairs 2017).

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 various neurological conditions such as progressive MS, 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 drug use disorders, neurodegenerative diseases (e.g., ALS and progressive MS), 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 drug use disorders, ALS, and progressive MS. MN-166 (ibudilast) was granted Fast-Track Designation for the treatment of methamphetamine dependence by the U.S. Food and Drug Administration.

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.*, alcohol use disorder, 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 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, 2016 and its subsequent periodic reports on Form 10-Q and current reports on Form 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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