MediciNova Announces Positive Interim Results of Phase 2a Study of MN-166 (ibudilast) in Opioid Dependence

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LA JOLLA, Calif., Aug. 18, 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 positive interim results of a Phase 2a clinical trial of MN-166 (ibudilast) in opioid dependence. The study is being conducted at Columbia University and the New York State Psychiatric Institute and led by Dr. Sandra Comer, Professor of Neurobiology. The interim analysis was performed after the first seven patients had completed the study, which required a 6-week stay on the inpatient unit.

MN-166 (ibudilast) demonstrated a number of beneficial effects on the subjective, analgesic, and reinforcing effects of oxycodone. MN-166 significantly decreased the craving for heroin ($p<0.05$), cocaine ($p<0.05$), and tobacco ($p<0.05$). MN-166 also decreased the positive subjective effects of oxycodone measured by mean responses to statements such as "I Feel High" ($p<0.05$) and "I Liked the Dose" ($p<0.05$). MN-166 also enhanced the analgesic effects of oxycodone. MN-166 reduced the sum score on the McGill Pain Questionnaire, reduced the mean rating on the Painful scale, and reduced the mean rating on the Bothersome scale ($p<0.05$). Finally, MN-166 decreased the reinforcing effects of oxycodone.

Dr. Comer, principal investigator, commented, "We are excited to report these interim findings, and look forward to completion of the study and moving on to the next clinical trial of ibudilast." Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented "We are very pleased with the results of the interim analysis. We believe the craving data is particularly important, as it establishes that ibudilast has potential to be used as a long-term therapy to prevent relapses in recovering opioid-dependent patients." Dr. Iwaki further commented, "This data is complementary to the data from our previous study in heroin abusers, in which ibudilast demonstrated a reduction in withdrawal symptoms. The data also confirms the positive effects of ibudilast on analgesia which we have seen in a previous study."

About the Trial

The study is a randomized, placebo-controlled, double-blind, inpatient Phase 2a study of MN-166 (ibudilast) in opioid-dependent abusers of prescription opioids and/or heroin. The study duration is approximately 6 weeks per subject. The crossover study design includes initial detoxification followed by randomization to ibudilast 50 mg BID or placebo. Subjects are maintained on each dose for at least 2-3 consecutive weeks (1 week stabilization + 1.5 week testing). During test weeks, participants receive oxycodone (0, 15, or 30 mg PO) in random order on separate days. For each dose, a sample followed by a choice session is completed. During the choice session, a drug versus money self-administration paradigm is employed. The primary aim of the study is to investigate the ability of MN-166 to alter the reinforcing, analgesic, subjective, performance, and physiological effects of oxycodone, a commonly abused prescription opioid.

About MN-166 (ibudilast)

MN-166 has been marketed in Japan and Korea since 1989 to treat cerebrovascular disorders, including post-stroke complications, and bronchial asthma. MediciNova licensed MN-166 (ibudilast) from Kyorin Pharmaceutical for potential utility in MS. Intellectual property was additionally established or obtained by MediciNova in drug addiction, progressive MS and other neurological conditions. 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 including IL-1β, TNF-α, and IL-6, and which upregulates the release of the anti-inflammatory cytokine IL-10 and neurotrophic factors such as NGF and GDNF. It attenuates the activation of brain glial cells 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 progressive MS, drug 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, MN-221 for the treatment of acute exacerbations of asthma, and MN-001 for NASH and IPF. MN-166 is being developed in multiple indications, largely through investigator-sponsored trials and outside funding. MediciNova is engaged in strategic partnering 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. 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 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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