



National Institute on Alcohol Abuse and Alcoholism Funds New UCLA Clinical Trial of MediciNova's MN-166 in Treating Alcoholism

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Phase 2a Trial Initiating 4Q2013

LOS ANGELES and SAN DIEGO, Aug. 25, 2013 (GLOBE NEWSWIRE) -- The University of California, Los Angeles' (UCLA's) Departments of Psychology, and Psychiatry and Biobehavioral Sciences Brain Research Institute, and MediciNova, Inc. a biopharmaceutical company traded on the NASDAQ Global Market (Nasdaq:MNOV) and the Jsdq Market of the Osaka Securities Exchange (Code Number: 4875), today announced that the National Institute on Alcohol Abuse and Alcoholism (NIAAA), part of the National Institutes of Health, will fund a clinical trial of MN-166 (ibudilast) for alcohol dependence. The proposed trial has also completed FDA review. MediciNova previously announced an ongoing Phase 2a trial of MN-166 in opioid dependence with Columbia University investigators, and a UCLA Phase 2b trial in methamphetamine dependence anticipated to initiate enrollment later this quarter – both funded by the National Institutes of Drug Abuse (NIDA).

The alcohol dependence study will be led by Lara Ray, Ph.D., Associate Professor, Department of Psychology, Department of Psychiatry and Biobehavioral Sciences, and the UCLA Brain Research Institute. The trial follows recently completed studies supported by MediciNova's participation in NIAAA's Preclinical Medication Efficacy Testing Program and builds upon ongoing clinical development with other UCLA investigators within the addiction research group who are studying MN-166 in methamphetamine dependence. MediciNova will provide drug supply and regulatory support for the clinical trial.

"Emerging research in the field of alcohol dependence has identified some of the same molecular and cellular targets that have been implicated in drug addiction. These targets appear to be affected by ibudilast and are worthy of pharmacotherapy development for alcohol addiction," said Dr. Ray. The combination of the preclinical, NIAAA-sponsored alcohol dependence studies, along with the encouraging clinical development progress in drug addiction and other neurological conditions, provides a solid foundation for our initial clinical research. We are pleased to partner with NIAAA and MediciNova to help move forward the testing of MN-166 as a novel treatment for alcoholism."

"We are excited to expand our collaboration with UCLA and welcome the NIAAA to our MN-166 development efforts for addiction," said Dr. Yuichi Iwaki, President and CEO of MediciNova. "With MN-166 advancing in concurrent Phase 2 trials in three addiction indications as well as progressive multiple sclerosis, and with our MN-221 program slated for continuing development in acute exacerbations of asthma, MediciNova's pipeline continues to build bench strength. We look forward to continuing our relationship with both NIH and UCLA as we investigate the unique properties of MN-166 in addiction."

About alcohol addiction:

Alcohol use disorders are medical conditions affecting about 18 million people in the United States⁽¹⁾ and include alcohol abuse and alcohol dependence – better known as alcoholism. The economic cost of excessive drinking in the U.S. was recently estimated at \$223.5 billion per year⁽²⁾. Alcoholism, the more severe disorder, is a chronic disease marked by repeated alcohol use despite negative physical and psychosocial consequences. While there are some pharmacotherapies approved by the Food and Drug Administration (FDA) for the treatment of alcoholism, they are only modestly effective⁽³⁾. Accordingly, new directions in medication development have become a high priority amongst alcohol dependence researchers and the NIAAA.

About the trial:

This study involves the enrollment in a UCLA research unit of 24 non-treatment seeking individuals with either alcohol abuse or dependence. Participants will be randomly assigned to a 7-day treatment period involving repeat oral administration of either MN-166 escalated up to 100 mg/day or inactive control (placebo). During the treatment period, participants will take the study medication, complete an IV alcohol challenge, and take part in laboratory tests of alcohol craving as well as mood surveys and standard safety tests. Following a 7-10 day study break, trial participants will re-enroll for another 7-day period wherein they will cross over to the other treatment condition. The key study outcomes include safety, tolerability and preliminary efficacy as indicated by whether MN-166 reduces alcohol craving under controlled conditions. The outcomes of this trial will inform the feasibility of a Phase 2b, regulatory-track, outpatient trial in alcohol dependence.

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 in October 2004 for potential utility in relapsing remitting multiple sclerosis (RRMS). Intellectual property was additionally established by MediciNova in other neurological conditions. MN-166 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-1 β , 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/or neuroprotective actions have been demonstrated in preclinical and clinical study results and provide the rationale for its therapeutic utility in alcohol- or opioid- or methamphetamine addiction, progressive MS, and chronic neuropathic pain. MediciNova's development paths are firmly founded on issued method-of-use patents. A drug supply collaboration exists with Taisho Pharmaceutical Industries, Ltd., owned by Teva Pharmaceuticals.

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 need with a commercial focus on the U.S. market. MediciNova's current strategy is to focus on its two prioritized product candidates, MN-166 (ibudilast) for neurological disorders, and MN-221 for the treatment of acute exacerbations of asthma. MediciNova is engaged in strategic partnering and consortium funding discussions to support further development of both the MN-221 and ibudilast/MN-166 programs. For more information on MediciNova, Inc., please visit www.medicinova.com.

References:

1. NIAAA website.
2. Bouchery, E.E., et al., *Economic costs of excessive alcohol consumption in the U.S., 2006*. Am J Prev Med, 2011. **41**(5): p. 516-24.
3. Johnson, B.A., *Update on neuropharmacological treatments for alcoholism: scientific basis and clinical findings*. Biochem Pharmacol, 2008. **75**(1): p. 34-56.

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 our clinical development strategies, including future development, statements regarding the progress of clinical trials, statements regarding expectations for the ibudilast/MN-166 program, including development of ibudilast/MN-166 for certain indications and expectations on future progress in the development of our drug candidates, expected timing of clinical trial results and any implication as to the results of our development, partnering and funding efforts, the implication of patent terms and potential product exclusivity and the implication that the company will have the ability to execute on its priorities. 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," 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-221 and 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, 2012 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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