NIH Funds UCLA Phase 2 Study of MediciNova's MN-166 in Treating Drug Addiction

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Clinical Trial in Methamphetamine Addiction to Begin in Early 2013

LOS ANGELES and SAN DIEGO, Sept. 4, 2012 (GLOBE NEWSWIRE) -- The University of California, Los Angeles' (UCLA's) Department of Family Medicine/Center for Behavioral and Addiction Medicine, and MediciNova, Inc. a biopharmaceutical company traded on the NASDAQ Global Market (Nasdaq:MNOV) and the Jasdaq Market of the Osaka Securities Exchange (Code Number: 4875), today announced approval and funding by the National Institutes on Drug Abuse (NIDA), part of the National Institutes of Health, of a Phase 2 clinical trial studying the use of MN-166 (ibudilast) for the treatment of methamphetamine addiction. Building on an ongoing UCLA MN-166 Phase 1b safety trial, NIDA has now awarded grant funding for a statistically powered Phase 2 outpatient study in methamphetamine addicts. MediciNova will provide drug supply and regulatory support for the Phase 2 trial.

"UCLA has long recognized the danger of methamphetamine abuse, and NIDA has actively supported our research on understanding methamphetamine's effects on the brain and behavior in order to develop prevention and treatment strategies, including medications," said Steven Shoptaw, Ph.D., Professor, UCLA Departments of Family Medicine and Psychiatry and Biobehavioral Sciences. "Methamphetamine addiction is a tremendous societal burden and also contributes to healthcare costs from premature conditions such as heart attacks and strokes in relatively young patients to the increased transmission of infectious diseases, including HIV. We are pleased to partner with NIDA and MediciNova to help move forward this important study of MN-166 to test its potential utility in this devastating condition."

According to the Substance Abuse and Mental Health Services Administration (SAMHSA) and their National Survey on Drug Use and Health, 1.2 million Americans aged 12 years and older abused methamphetamine in the year prior to their 2009 survey. An independent study conducted by the Rand Corporation estimated the overall cost impact of methamphetamine use in the U.S. "reached more than an estimated $23.4 billion in 2005."

"Preclinical studies have shown that MN-166 may prevent the activation of certain cells in the central nervous system, called glial cells, that have been linked to drug dependence. We are very excited to move this promising molecule into a Phase 2 clinical trial in partnership with MediciNova and NIDA," said UCLA's Keith Heinzerling, M.D., Assistant Professor, UCLA Department of Family Medicine, Medical Director, UCLA Center for Behavioral and Addiction Medicine, and principle investigator of the trial. "This study has real public health relevance because a medication treatment may improve health outcomes and reduce the public health burden of methamphetamine dependency, especially those with HIV infection, where there is high risk of co-morbidity."

"We are excited to collaborate with the expertise of NIDA and UCLA in studying the potential of MN-166 for methamphetamine addiction," said Dr. Yuichi Iwaki, President and CEO of MediciNova. "Along with our lead clinical program, MN-221 for acute exacerbation of asthma, the broad potential of MN-166 for drug addiction, progressive multiple sclerosis, and neuropathic pain represents a core focus of our development efforts."

About the Trial

The Phase 2 trial will study the safety and efficacy of MN-166 (ibudilast) for the treatment of methamphetamine dependence in treatment-seeking volunteers (N = 140) who will be randomly assigned 1:1 to MN-166 at a dose of 100 mg/day or matching placebo. Half of the trial participants in each treatment group will have a co-diagnosis of HIV as methamphetamine addiction in HIV-positive individuals is a growing issue. During the 12-week outpatient study, dependent subjects will participate in thrice-weekly clinic visits for health checkups, counseling, urine drug screens, and medication adherence monitoring. The study is powered 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 – an outcome favored by regulatory authorities for addiction medication assessment. Additional endpoints include the effect of ibudilast on methamphetamine use and neurocognitive performance as well as regulation of HIV-associated factors such as T-cell counts and sexual behavior.

For more information on the MN-166 Phase 2 clinical trial, please visit http://clinicaltrials.gov.

About Methamphetamine and Addiction

Source NIDA

Methamphetamine is a very addictive stimulant that is closely related to amphetamine. It is long lasting and toxic to dopamine nerve terminals in the central nervous system. It is a white, odorless, bitter-tasting powder taken orally or by snorting or injecting, or a rock "crystal" that is heated and smoked.

Methamphetamine increases wakefulness and physical activity, produces rapid heart rate, irregular heartbeat, and increased blood pressure and body temperature. Long-term use can lead to mood disturbances, violent behavior, anxiety, confusion, insomnia, and severe dental problems. All users, but particularly those who inject the drug, risk infectious diseases such as HIV/AIDS and hepatitis.

About MN-166 (ibudilast)

MN-166 has been marketed in Japan and Korea since 1989 to treat cerebrovascular disorders, such as stroke, and bronchial asthma. MediciNova licensed MN-166 (ibudilast), from Kyorin Pharmaceutical in October 2004 for potential utility in relapsing remitting multiple sclerosis. MediciNova scientists and collaborators independently established evidence of ibudilast utility in opioid and methamphetamine addiction.

MN-166 is a first-in-class, orally bioavailable small molecule and an attenuator of glial cell activation – a physiological alteration that has been linked to certain drug dependence situations. Indeed, activation of human brain glial cells has been documented in imaging studies of methamphetamine addicts ("Methamphetamine Causes Microglial Activation in the Brains of Human Abusers" Journal of Neuroscience, May 28, 2008, v.28 (22),

pp.5756-5761)

MN-166 is a phosphodiesterase (PDE) -4 and -10 inhibitor and a macrophage migration inhibitory factor (MIF) inhibitor that suppresses pro-inflammatory cytokines including IL-1ß, TNF-a, and IL-6, and may upregulate the anti-inflammatory cytokine IL-10 and neurotrophic factors. It has additionally been shown to be a toll-like receptor 4 (TLR4) functional antagonist that may contribute to its therapeutic action.

MediciNova's development efforts in progressive MS and chronic neuropathic pain is also founded upon both preclinical and clinical data indicating anti-neuroinflammatory and neuroprotective actions, which may be beneficial in those conditions.

About the MN-166 Phase 1b Safety Study

UCLA is currently conducting a Phase 1b study. As previously reported, 12 methamphetamine-dependent participants who are not looking for treatment will complete a sequence of randomized crossover between placebo and low and high MN-166 dosing regimens over nearly a month time frame in a hospital study unit. At defined intervals, the subjects will receive controlled methamphetamine exposures. The primary objective is to assess the safety and tolerability of MN-166 up to 100 mg daily oral doses alone and in combination with methamphetamine administration. Secondary outcomes will include measures of dependence and cognition.

About UCLA Department of Family Medicine/Center for Behavioral and Addiction Medicine

The mission of the Center for Behavioral and Addiction Medicine is to advance the prevention and treatment of chronic illnesses, especially in communities with healthcare disparities. The Center integrates scientific and technological advancements from the best in academia with the strength of communities in its effort to conduct research, to engage health service partners in the use of innovative treatment options, and to disseminate prevention tools.

The work focuses on two of today's most severe chronic health problems, addiction and HIV/AIDS. We are conducting research to find effective interventions for these diseases, whether they are new medications, behavioral therapies, or a combination of the two. We are providing direct patient services in underserved communities. We are also training the next generation of physicians to diagnose and treat these illnesses in their practices.

For more information, please visit: http://fm.mednet.ucla.edu/CHPDP/chpdp.asp

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. Through strategic alliances primarily with Japanese pharmaceutical companies, MediciNova holds rights to a diversified portfolio of clinical and preclinical product candidates, each of which MediciNova believes has a well-characterized and differentiated therapeutic profile, attractive commercial potential, and patent coverage of commercially adequate scope. MediciNova's pipeline includes six clinical-stage compounds for the treatment of acute exacerbations of asthma, chronic obstructive pulmonary disease exacerbations, multiple sclerosis and other neurologic conditions, asthma, interstitial cystitis, solid tumor cancers, generalized anxiety disorder, preterm labor and urinary incontinence and two preclinical-stage compounds for the treatment of thrombotic disorders. MediciNova's current strategy is to focus on its two prioritized product candidates, MN-221, for the treatment of acute exacerbations of asthma and chronic obstructive pulmonary disease exacerbations, and ibudilast (MN-166) for neurological disorders. MN-221 is involved in clinical trials under U.S. INDs. MN-166 is being developed in Phase 1b/2 trials for pain and drug addiction, largely through Investigator INDs and outside funding. Proof-of-concept Phase 2b trial(s) in Progressive MS are pending. MediciNova is engaged in strategic partnering and consortium funding discussions to support further development of both the MN-221 and ibudilast/MN-166 programs. Additionally, MediciNova will seek to monetize opportunistically its other pipeline candidates. For more information on MediciNova, Inc., please visit www.medicinova.com.

The MediciNova, Inc. logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=3135

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 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 or 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 and uncertainties inherent in clinical trials including 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, cost and design of future clinical trials and research activities, 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 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, 2011 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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