National Institute on Alcohol Abuse and Alcoholism Awards R01 Research Grant to UCLA for Phase 2b Clinical Trial of MediciNova's MN-166 (ibudilast) in Alcohol Use Disorder

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LA JOLLA, Calif., Aug. 20, 2018 (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 the National Institute on Alcohol Abuse and Alcoholism (NIAAA), which is part of the National Institutes of Health (NIH), will fund a Phase 2b clinical trial to evaluate MN-166 (ibudilast) as a potential treatment to decrease alcohol consumption in treatment-seeking patients with alcohol use disorder (AUD). This study is a randomized, double-blind, placebo-controlled outpatient trial which will enroll up to 132 patients. The NIAAA R01 research funding was awarded to Principal Investigator Dr. Lara Ray, PhD, ABPP, at the University of California, Los Angeles' (UCLA) Departments of Psychology, and Psychiatry and Biobehavioral Sciences Brain Research Institute, based on her recent findings that MN-166 (ibudilast) was associated with mood improvements during stress- and alcohol-cue exposures, significantly decreased alcohol-induced stimulation and positive mood, decreased overall craving for alcohol in non-treatment seeking volunteers, and was safe and well-tolerated.

MediciNova will provide drug supply and regulatory support for the clinical trial.

MediciNova recently announced in May 2018 that it plans to initiate a separate clinical trial evaluating MN-166 in alcohol dependence and withdrawal in approximately 50 non-treatment seeking individuals with moderate-to-severe AUD with Dr. Ray and her research group. This study is funded by the NIH's National Institute on Drug Abuse (NIDA).

Lara Ray, PhD, Principal Investigator of the trial, commented "We are encouraged by the clinical data from our first study of ibudilast in AUD as it is a safe and promising compound for the treatment of AUD. If MN-166 (ibudilast) is able to reduce drinking compared to placebo in this new study, it will set the stage for a pivotal multi-site clinical trial leading to potential FDA approval of a novel AUD treatment."

Dr. Yuichi Iwaki, President and CEO of MediciNova, commented, "We are excited to continue our collaboration with UCLA and are very pleased that NIAAA continues to support our MN-166 development efforts for AUD."

About the R01 Research Grant

The Research Project Grant (R01) is the original and historically oldest grant mechanism used by NIH. The R01 provides support for health-related research and development based on the mission of the NIH. The Research Project (R01) grant is an award made to support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing the investigator's specific interest and competencies, based on the mission of the NIH.

About the Alcohol Use Disorder Trial

This study is a randomized, double-blind, placebo-controlled, outpatient clinical trial which will enroll up to 132 treatment-seeking men and women with moderate or severe AUD. Subjects will take MN-166 (ibudilast) 50 mg or placebo twice a day for 12 weeks. Subjects will complete the NIAAA-developed web-based program Take Control during the study. The primary endpoint of the trial is to test whether MN-166 (ibudilast) will decrease percent heavy drinking days (defined as ≥ 5 drinks for men and ≥ 4 drinks for women), as compared to placebo, over the course of the 12-week trial. The secondary endpoints are to test the efficacy of MN-166 (ibudilast) on 1) the number of drinks consumed per day, 2) the number of drinks consumed per drinking day, 3) the percentage of days abstinent, 4) the percentage of subjects with no heavy drinking days, and 5) the percentage of subjects who are abstinent, as well as measures of alcohol craving and negative mood, over the course of the 12-week trial. Exploratory endpoints include evaluation of whether the effects of MN-166 (ibudilast) on the primary and secondary endpoints are moderated by depressive symptomatology and whether MN-166 (ibudilast) reduces neuroinflammation over the course of the 12-week trial.

About Alcohol Use Disorder

Alcohol use disorder (AUD) is a prevalent and disabling psychiatric disorder with limited treatment options. AUD is a chronic relapsing brain disease characterized by compulsive alcohol use, loss of control over alcohol intake, and a negative emotional state when not using alcohol. According to the National Institute on Alcohol Abuse and Alcoholism (NIAAA), an estimated 16 million people in the U.S. have AUD and less than 10% receive treatment for the disease. There is a high unmet medical need for better treatments for AUD.

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-1ß, TNF-a, 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 medical needs with a primary commercial focus on the U.S. market. MediciNova's current strategy is to focus on MN-166 (ibudilast) for neurological disorders such as progressive multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS) and substance dependence (e.g., alcohol use disorder, 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, 2017 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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