MediciNova Announces the Presentation of Positive Results from Phase 2 Trial of MN-166 (ibudilast) in Alcohol Use Disorder at the American Psychological Association 2020 Annual Convention

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LA JOLLA, Calif., Aug. 06, 2020 (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 Principal Investigator, Lara Ray, PhD, Professor at the Department of Psychology, University of California Los Angeles (UCLA) presented the results of the Ibudilast and Alcohol Use Disorder Phase 2 trial at the American Psychological Association 2020 Annual Convention held online.

The clinical trial is a collaborative effort between MediciNova and Dr. Lara Ray, Professor, Department of Psychology and Department of Psychiatry and Biobehavioral Sciences, Brain Research Institute at UCLA and is funded by the Center for Study of Opioid Receptors and Drugs of Abuse (CSORDA; National Institute on Drug Abuse Grant P50-DA005010). This study was a randomized, double-blind, placebo-controlled Phase 2 trial to evaluate the effect of 14 days of ibudilast treatment on heavy drinking days and alcohol neural cue reactivity, and to test if neural activation to alcohol cues, evaluated by functional magnetic resonance (fMRI) neuroimaging, is predictive of drinking outcomes. A total of 52 alcohol use disorder (AUD) patients were enrolled in this trial.

The highlights of Dr. Ray's presentation are as follows:

- Drinking Outcomes: Ibudilast significantly reduced the number of heavy drinking days compared to placebo (p=0.03)
- Alcohol Neural Cue Reactivity: There was a significant effect of ibudilast on alcoholic beverage images (ALC) vs. non-alcoholic beverage images (BEV) percent signal change in the bilateral ventral striatum (VS) evaluated by fMRI (p=0.02)
    - Ibudilast attenuated alcohol cue-elicited activation in the VS relative to placebo
- Predicting Drinking by Medication: Significant interaction between ibudilast and activation in the VS on subsequent drinking (p=0.02)
    - Patients treated with ibudilast and had attenuated VS activation drank the least in the week after the scan
- Illustrates how neuroimaging (alcohol cue reactivity paradigm) can help inform the neurobiological mechanism of action of a novel pharmacotherapy

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc. commented, "We are extremely pleased with the positive results from the UCLA alcohol use disorder Phase 2 trial conducted by Dr. Ray. This is the first study to show the positive effect of MN-166 to attenuate activation in the brain in a neuroimaging study. It is quite impressive that ibudilast significantly reduced binge drinking after only 14 days of treatment. According to Nielsen, alcohol sales in stores were up 54% in late March compared to a year ago, online sales were up nearly 500% in late April compared to a year ago, and there has been unprecedented demand for larger pack sizes of wine and spirits. According to the American Heart Association, the COVID-19 pandemic brings new concerns about excessive drinking. We are thrilled that MN-166 has demonstrated great potential to reduce the increasing problem of alcohol use disorder."

Professor Lara Ray commented, "We are very excited to report the positive data from our Phase 2 clinical trial in AUD. Our first clinical trial demonstrated that ibudilast significantly reduced basal, daily alcohol craving in AUD patients. In the current study, we found that ibudilast improved drinking outcomes and reduced the rewarding response to alcohol in the brain of AUD patients, which demonstrates its potential as a novel AUD pharmacotherapy."

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

MN-166 (ibudilast) has been marketed in Japan and Korea since 1989 to treat post-stroke complications and bronchial asthma. MN-166 (ibudilast) is a first-in-class, orally bioavailable, small molecule phosphodiesterases (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 substance use disorders, neurodegenerative diseases (e.g., ALS and progressive MS), and chronic neuropathic pain. MediciNova is developing MN-166 for various neurological conditions such as progressive MS, ALS and substance abuse/addiction as well as prevention of acute respiratory distress syndrome (ARDS) caused by COVID-19.

About MediciNova

MediciNova, Inc. is a publicly traded biopharmaceutical company focused on developing novel therapeutics for the treatment of diseases with high unmet medical needs with a primary commercial focus on the U.S. market. MediciNova's current strategy is to focus on BC-PIV vaccine for COVID-19, MN-166 (ibudilast) for neurological disorders such as progressive multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), degenerative cervical myelopathy (DCM), glioblastoma (GBM), and substance dependence (e.g., alcohol use disorder, methamphetamine dependence, opioid dependence), as well as prevention of acute respiratory distress syndrome (ARDS) caused by COVID-19, 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) and MN-029 (denibulin). 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 BC-PIV vaccine, MN-166, MN-001, MN-221, 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-001, MN-221, 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, 2019 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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