MediciNova Announces Positive Results from Phase 2 Trial of MN-166 (ibudilast) in Alcohol Use Disorder Published in Nature's Translational Psychiatry Journal

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LA JOLLA, Calif., June 21, 2021 (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 positive results from a Phase 2 trial of MN-166 (ibudilast) in alcohol use disorder (AUD) were published in Nature's *Translational Psychiatry*.

The clinical trial was a collaborative effort between MediciNova and Dr. Lara Ray, Professor, Department of Psychology and Department of Psychiatry and Biobehavioral Sciences, Brain Research Institute at the University of California at Los Angeles (UCLA) and was 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 mood, heavy drinking, and neural reward signals in individuals with AUD. A total of 52 AUD patients were enrolled in this trial.

The publication, entitled "Ibudilast, a neuroimmune modulator, reduces heavy drinking and alcohol cue-elicited neural activation: a randomized trial" was authored by Dr. Lara Ray and colleagues at UCLA.

Key results reported in the publication include the following:

- Ibudilast did not have a significant effect on negative mood.
- Ibudilast, relative to placebo, reduced the odds of heavy drinking across time by 45% (OR=0.55, (95% CI: 0.30, 0.98)).
- Ibudilast attenuated alcohol cue-elicited activation in the ventral striatum (VS) compared to placebo (p=0.01).
- Alcohol cue-elicited activation in the VS predicted subsequent drinking in the ibudilast group (p=0.02), such that individuals who had attenuated ventral striatal activation and took ibudilast had the fewest number of drinks per drinking day in the week following the scan.
- Ibudilast reduced alcohol craving compared to placebo on non-drinking days (p=0.02).
- These findings extend preclinical and human laboratory studies of the utility of ibudilast to treat AUD and suggest a biobehavioral mechanism through which ibudilast acts, namely, by reducing the rewarding response to alcohol cues in the brain leading to a reduction in heavy drinking.

Kazuko Matsuda, MD, PhD, MPH, Chief Medical Officer of MediciNova, Inc., commented, "We are very pleased that the results from this Phase 2 trial in alcohol use disorder have been published. We are excited that MN-166 reduced the odds of heavy drinking by 45% after only 14 days of treatment. Our first clinical trial demonstrated that ibudilast significantly reduced basal, daily alcohol craving in AUD patients. We are thrilled that MN-166 has demonstrated great potential to reduce the increasing problem of alcohol use disorder."

Professor Lara Ray commented, "During the COVID-19 pandemic, uncertainty, unemployment, and isolation were factors that increased anxiety and stress, and led to new cases of alcohol misuse and AUD. Our findings from this Phase 2 clinical trial—ibudilast improved drinking outcomes and reduced the rewarding response to alcohol in brains of individuals with AUD—are timely and very encouraging for the treatment of AUD."

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 (ibudilast) is a small molecule compound that inhibits phosphodiesterase type-4 (PDE4) and inflammatory cytokines, including macrophage migration inhibitory factor (MIF). It is in late-stage clinical development for the treatment of neurodegenerative diseases such as ALS (amyotrophic lateral sclerosis), progressive MS (multiple sclerosis), and DCM (degenerative cervical myelopathy); and for glioblastoma, CIPN (chemotherapy-induced peripheral neuropathy), and substance use disorder. In addition, MN-166 (ibudilast) is being evaluated in patients that are at risk for developing acute respiratory distress syndrome (ARDS).

About MediciNova

MediciNova, Inc. is a clinical-stage biopharmaceutical company developing a broad late-stage pipeline of novel small molecule therapies for inflammatory, fibrotic and neurodegenerative diseases. Based on two compounds, MN-166 (ibudilast) and MN-001 (tipelukast), with multiple mechanisms of action and strong safety profiles, MediciNova has 11 programs in clinical development. MediciNova's lead asset, MN-166 (ibudilast), is currently in Phase 3 for amyotrophic lateral sclerosis (ALS) and degenerative cervical myelopathy (DCM), and is Phase 3-ready for progressive multiple sclerosis (MS). MN-166 (ibudilast) is also being evaluated in Phase 2 trials in glioblastoma, patients at risk of developing acute respiratory distress syndrome (ARDS), and substance dependence. MN-001 (tipelukast) is being evaluated in a Phase 2 trial in idiopathic pulmonary fibrosis (IPF) and is in preparation for a second Phase 2 trial in nonalcoholic steatohepatitis (NASH). MediciNova has a strong track record of securing investigator-sponsored clinical trials funded through government grants.

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-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, 2020 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.

INVESTOR CONTACT:
Geoff O'Brien
Vice President
MediciNova, Inc.
info@medicinova.com

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