MediciNova Announces Positive Results from Secondary Analysis of Phase 2 Trial of MN-166 (ibudilast) Published in The American Journal of Drug and Alcohol Abuse

December 5, 2022

LA JOLLA, Calif., Dec. 05, 2022 (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 secondary analysis of a Phase 2 trial of MN-166 (ibudilast) in alcohol use disorder (AUD) were published in *The American Journal of Drug and Alcohol Abuse*.

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 National Institute on Drug Abuse (Grant P50 DA005010-33). Topline results from a randomized, double-blind, placebo-controlled Phase 2 trial evaluating the effect of 14 days of ibudilast treatment on mood, heavy drinking, and neural reward signals in 52 non-treatment seeking individuals with AUD found that MN-166 (ibudilast) reduced heavy drinking and attenuated neural cue-reactivity compared to placebo (Grodin et al, Transl Psychiatry, 2021).

Neural and peripheral inflammation has been implicated in the development and maintenance of AUD, as evidenced by increased inflammation in such individuals. A secondary analysis of this study was performed to determine if participants with elevated peripheral levels of proinflammatory proteins, specifically C-reactive protein (CRP), would show a greater benefit from MN-166 (ibudilast) as assessed by clinical (drinks per drinking day, or DPDD; percent heavy drinking days, or PHDD) and biological (cue-elicited neural activation) outcomes.

The publication, entitled, “Baseline C-reactive protein levels are predictive of treatment response to a neuroimmune modulator in individuals with an alcohol use disorder: a preliminary study,” was authored by Dr. Lara Ray and colleagues at UCLA.

Key results reported in the publication are as follows:

- Participants with high baseline CRP, i.e., high inflammation, had higher baseline DPDD and PHDD relative to the low baseline CRP group.
- The high baseline CRP group who received MN-166 (ibudilast) had significantly fewer DPDD compared to the low baseline CRP group ($p = 0.007$) who received MN-166 (ibudilast).
- No significant differences on DPDD were found between any other groups (p’s >0.17).
- There was also a significant interaction between MN-166 (ibudilast) and continuous log CRP levels on DPDD ($p = 0.03$).
- The low baseline CRP group treated with MN-166 (ibudilast) had greater alcohol cue-elicited activation (i.e. reward signaling) in several brain regions relative to the high baseline CRP group treated with MN-166 (ibudilast) ($p <0.001$).
- The high baseline CRP group treated with placebo had greater alcohol cue-elicited activation in several brain regions relative to the high baseline CRP group treated with MN-166 (ibudilast) ($p <0.001$).
- The high baseline CRP group treated with placebo had greater alcohol cue-elicited activation in several brain regions relative to the low baseline CRP group treated with placebo ($p <0.001$).

Kazuko Matsuda, MD, PhD, MPH, Chief Medical Officer of MediciNova, Inc. commented, “We are very pleased that this secondary analysis of the results of this Phase 2 trial in alcohol use disorder have been published. We are thrilled that MN-166 appeared to show great potential clinical utility in individuals with an AUD who also have elevated inflammation, thereby increasing the probability of successful outcomes in the treatment of AUD.”

Professor Lara Ray commented, “Results from this Phase 2 clinical trial reinforce the theory that inflammation plays a role in the effect of MN-166 (ibudilast) treatment on alcohol consumption, implying that individuals with elevated baseline CRP levels benefitted the most from MN-166 (ibudilast) as shown by lower DPDD, PHDD, and lower alcohol cue-elicited activation.”

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 14.5 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 is also in development for glioblastoma, CIPN (chemotherapy-induced peripheral neuropathy), and substance use disorder. In addition, MN-166 (ibudilast) was 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 and substance dependence. MN-001 (tipelukast) was evaluated in a Phase 2 trial in idiopathic pulmonary fibrosis (IPF) and a second Phase 2 trial in non-alcoholic fatty liver disease (NAFLD) is ongoing. 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, 2021 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

Source: MediciNova, Inc.