MediciNova Announces Secondary Analysis of Phase 2 Trial of MN-166 (ibudilast) in Alcohol Use Disorder Published in Alcoholism: Clinical and Experimental Research

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LA JOLLA, Calif., April 07, 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 a secondary analysis of a Phase 2 clinical trial of MN-166 (ibudilast) in alcohol use disorder (AUD) was published in the journal *Alcoholism: Clinical and Experimental Research*.

The publication entitled, "The effect of neuroimmune modulation on subjective response to alcohol in the natural environment," co-authored by MediciNova's collaborator, Dr. Lara Ray, Professor, Department of Psychology and Department of Psychiatry and Biobehavioral Sciences, Brain Research Institute at the University of California, Los Angeles and colleagues, describes a secondary analysis of a two-week clinical trial of MN-166 (ibudilast) that enrolled 52 non-treatment seeking participants with AUD.

Eligible participants were randomized to MN-166 (ibudilast) or matched placebo and completed daily diary assessments (DDAs) during the two-week period. Each morning, participants retrospectively reported on their mood and craving levels both before and during the previous day's drinking episode, as well as stimulation and sedation levels during the previous day's drinking episode. Multilevel models compared the effects of MN-166 (ibudilast) and placebo on subjective alcohol response. Exploratory analyses evaluated whether MN-166 (ibudilast) moderated the relationship between daily stimulation / sedation and alcohol intake and whether withdrawal-related dysphoria moderated the effects of MN-166 (ibudilast) on subjective response.

Key take-aways about MN-166 (ibudilast) in the publication include:

- Initial findings showed that MN-166 (ibudilast), a neuroimmune modulator, reduces rates of heavy drinking and measures of alcohol craving
- MN-166 (ibudilast) did not significantly alter mean levels of stimulation or sedation
- MN-166 (ibudilast) moderated the effect of daily stimulation on same-day number of drinks consumed (p=0.045)
- MN-166 (ibudilast) attenuated alcohol-induced increases in craving compared with placebo (p=0.047) but no other subjective response measures
- MN-166 (ibudilast) may reduce the acute and chronic proinflammatory effects of alcohol, either indirectly through suppression of peripheral inflammation or directly by altering cAMP signaling pathways and suppressing cytokine expression and in the brain (e.g., rewards regions relevant to craving)
- Among individuals without withdrawal-related dysphoria, MN-166 (ibudilast) significantly tempered daily alcohol-induced changes in urge to drink (p=0.021) and positive mood (p=0.001)
- This tempering of alcohol's effects may reflect MN-166 (ibudilast)'s enhancement of anti-inflammatory and neurotrophic factors suspected to impact dopaminergic signaling in rewards regions, such as the nucleus accumbens, where PDE4 and PDE10 are highly expressed
- Consistent with previous findings, reductions in alcohol craving may represent a primary mechanism of MN-166 (ibudilast)

Kazuko Matsuda, MD, PhD, MPH, Chief Medical Officer of MediciNova, Inc. commented, "The primary analysis of this Phase 2 clinical trial showed that MN-166 reduced alcohol craving on non-drinking days (p=0.02), reduced the odds of heavy drinking by 45% (p=0.04), and attenuated neural response to alcohol cues (p=0.01). We are pleased that the results of this secondary analysis are consistent with the findings from the primary analysis."

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), in 2019, an estimated 14.5 million people ages 12 and older in the U.S. have AUD, less than 8% receive treatment for the disease, and less than 4% of people with AUD were prescribed a medication approved by the FDA to treat their disorder. There is a high, unmet medical need for better and more accessible 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) was evaluated in a Phase 2 trial in idiopathic pulmonary fibrosis (IPF) and is in preparation for a second Phase 2 trial related to 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, 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.

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