MediciNova Announces MN-166 (ibudilast) Identified as Promising Pharmacotherapy for Alcohol Use Disorder in Drugs

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LA JOLLA, Calif., Feb. 22, 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 MN-166 (ibudilast) was discussed as one of the promising pharmacological agents for the treatment of alcohol use disorder (AUD) in the journal *Drugs*.

The publication entitled "Novel Agents for the Pharmacological Treatment of Alcohol Use Disorder," 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, identified drug candidates with potential clinical utility, and among the many compounds reviewed, named MN-166 (ibudilast) as one of the promising treatments for AUD with clinical findings that warrant further investigation for the treatment of this highly prevalent, chronic, and relapsing condition.

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

- Preclinical findings which demonstrate that MN-166 (ibudilast) reduces alcohol intake align with prior studies in which pharmacological inhibition of PDE also reduced alcohol intake
- MN-166 (ibudilast) improves mood during exposure to alcohol and stress cues, and reduces the mood-altering and stimulant effects of alcohol among participants with more severe depressive symptoms
- MN-166 (ibudilast) reduces alcohol craving on non-drinking days, reduces the odds of heavy drinking by 45%, and attenuates neural response to alcohol cues
- MN-166 (ibudilast) acts similarly to naltrexone, one of the few FDA-approved treatments for AUD, in terms of reducing the rewarding effects of alcohol
- MN-166 (ibudilast) has been evaluated in the AUD target population, compared to several agents still in preclinical development
- As neuroinflammation is observed in AUD, the effects of MN-166 (ibudilast) in treating AUD are thought to be driven by its anti-inflammatory and pro-neurotrophic properties.
- MN-166 (ibudilast) appears to be well tolerated

Kazuko Matsuda, MD, PhD, MPH, Chief Medical Officer of MediciNova, Inc. commented, "We are encouraged that ibudilast, deservedly so, was identified by this highly esteemed group of researchers as a promising pharmacotherapy for treatment of AUD, an often debilitating, refractory disease."

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) 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, 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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