



MediciNova to Support NIH-Funded Expanded Access Clinical Trial to Evaluate MN166 (ibudilast) in Amyotrophic Lateral Sclerosis (ALS)

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Academic group to receive a total of \$22 million for the trial

LA JOLLA, Calif., Sept. 30, 2024 (GLOBE NEWSWIRE) -- MediciNova, Inc., a biopharmaceutical company traded on the NASDAQ Global Market (NASDAQ:MNOV) and the Standard Market of the Tokyo Stock Exchange (Code Number: 4875), today announced that the National Institutes of Health (NIH) - Neurological Disorders and Stroke (NINDS) has awarded \$22 million for an intermediate size Expanded Access Protocol (EAP) to evaluate the efficacy of MN-166 (ibudilast) in Amyotrophic Lateral Sclerosis (ALS)^{1,2}. In collaboration with an academic group, MediciNova will provide investigational drug MN-166 (ibudilast), regulatory support, and safety monitoring support.

The NIH grant is supported by the Accelerating Access to Critical Therapies for ALS Act (ACT for ALS) signed into law by President Biden. Expanded Access, also referred to as Compassionate Use, is an FDA-regulated pathway that allows individuals with a serious and life-threatening disease to access an investigational drug that is not yet approved by the FDA. This EAP trial will allow individuals with ALS who are not eligible to participate in the COMBAT-ALS trial to receive treatment with MN-166. The EAP will evaluate neurofilament light, a biomarker for neuron damage, and clinical data in two hundred (200) ALS patients treated with MN-166.

Dr. Yuichi Iwaki, MediciNova's President and CEO commented, "The NIH/NINDS grant, and the academic collaboration are significant steps forward in the endeavor to find a solution to this devastating disease. We are honored to support this EAP trial, which will provide MN-166 (ibudilast) to more individuals in advanced stages of ALS who are not eligible to current Phase 2/3 COMBAT-ALS trial. We extend our sincere gratitude to the NIH and NINDS for their support through the Act for ALS. Additionally, we deeply appreciate the participants and their families, as well as the healthcare providers and staff at the site, whose efforts will make this EAP possible, thereby advancing our understanding of MN-166 (ibudilast) as a potential therapy for ALS."

About MN-166 (ibudilast)

MN-166 (ibudilast) is an orally available 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, Long COVID, 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).

MediciNova holds Orphan Drug Designation for MN-166 (ibudilast) in ALS by U.S. FDA and EU EMA. MN-166 (ibudilast) has received Fast Track Designation by FDA for treatment of ALS. In addition, MN-166 (ibudilast) holds Orphan Disease Designation for the treatment of Glioblastoma.

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 Long COVID 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, 2023 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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¹ <https://newsnetwork.mayoclinic.org/discussion/mayo-clinic-awarded-federal-grant-to-study-experimental-als-drug/>

² <https://www.ninds.nih.gov/news-events/directors-messages/all-directors-messages/updates-act-als>



Source: MediciNova, Inc.