MediciNova Announces 100 Patients Enrolled in SEANOBI Study Expanded-Access-Program (EAP) Evaluating MN-166 (ibudilast) in ALS patients

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LA JOLLA, Calif., Jan. 29, 2026 (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 as of the end of January 2026, 12 sites in the US are activated and 100 patients have been enrolled in the SEANOBI study (Scalable Expanded Access with Analysis of Neurofilament and Other Biomarkers in ALS; NCT 06743776) representing 50% of the planned 200-enrollment, evaluating MN-166 (ibudilast) in patients with amyotrophic lateral sclerosis (ALS).

Dr. Yuichi Iwaki, President and CEO of MediciNova, commented: “Achieving 100 enrolled patients in the NIH-funded SEANOBI Expanded-Access Program marks substantial progress in the clinical development of MN-166. We are deeply grateful to the patients and families who chose to participate in SEANOBI, as their commitment makes this important program possible. We also sincerely appreciate the continued support from NINDS under the ACT for ALS initiative, which has enabled to expand access to MN-166 while gathering meaningful clinical and biomarker insights. Together with our COMBAT-ALS study, SEANOBI brings forward both clinical and real-world evidence that will support discussions with regulators. We believe these combined data along with having Orphan Drug Designation from FDA and EMA and Fast Track Designation from FDA, will help us advance MN-166 one step closer to becoming an approved treatment option for people living with ALS, who urgently need more choices.”

The NIH-funded SEANOBI Expanded-Access Program (EAP), supported by a $22 million NINDS grant under ACT for ALS, is designed to offer MN-166 (ibudilast) treatment access to individuals living with ALS who are not eligible to participate in ongoing randomized clinical trials. while also generating important biomarker and clinical outcome data from a real-world ALS population.

MN-166 (ibudilast) is also being evaluated in the COMBAT-ALS Phase 2b/3 trial, a randomized, placebo-controlled study assessing MN-166’s efficacy and safety in ALS. The study includes a 12-month double-blind period followed by a 6-month open-label extension, with 234 patients enrolled in the U.S. and Canada. Top-line results are expected by the end of 2026.

About SEANOBI-ALS

The SEANOBI Expanded-Access Program (EAP) is a U.S.-based initiative funded by a $22 million NINDS/NIH grant under ACT for ALS, designed to provide MN-166 (ibudilast) to individuals living with ALS who are not eligible for ongoing randomized clinical trials. The program aims to enroll approximately 200 patients across 12 active sites and is structured to collect valuable real-world clinical outcomes and biomarker data, including neurofilament levels.

About COMBAT-ALS

COMBAT-ALS is MediciNova’s ongoing Phase 2b/3 randomized, double-blind, placebo-controlled clinical trial evaluating the efficacy, safety, and tolerability of MN-166 (ibudilast) in individuals with amyotrophic lateral sclerosis. A total of 234 patients have been randomized across clinical sites in the United States and Canada. The study includes a 12-month double-blind treatment period, followed by a 6-month open-label extension. Top-line results are expected by the end of 2026. COMBAT-ALS is designed to generate the controlled-trial evidence necessary to support MN-166’s potential future approval for the treatment of ALS.

References

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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 and MN-001. 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 and MN-001, 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, 2024 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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