MediciNova Announces New Data and Results of a Phase 2 Clinical Trial of MN-166 (ibudilast) in Glioblastoma Presented at the 28th Annual Meeting of the Society for Neuro-Oncology

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LA JOLLA, Calif., Nov. 19, 2023 (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 MediciNova's collaborator, Justin Lathia PhD, Co-Director of the Brain Tumor Research and Therapeutic Development Center of Excellence at Cleveland Clinic Lerner Research Institute, and Professor, Department of Molecular Medicine at Cleveland Clinic Lerner College of Medicine of Case Western Reserve University, and Patrick Wen, Director at the Center for Neuro-Oncology at Dana-Farber Cancer Institute, Professor of Neurology, Harvard Medical School, presented new data and results of a Phase 2 clinical trial of MN-166 (ibudilast) in glioblastoma (GBM) patients at the 28th Annual Meeting of the Society for Neuro-Oncology (SNO) held November 15 - 19, 2023 in Vancouver, Canada. The presentation also included data from preclinical studies which evaluated the combination of MN-166 (ibudilast) and anti-PD1 or anti-PD-L1 therapy in GBM models.

The primary endpoints of this Phase 2 clinical trial were safety and tolerability of MN-166 (ibudilast) and temozolomide (TMZ) combination treatment and efficacy of the combination treatment defined as progression-free survival rate at 6 months using the RANO criteria. MN-166 (ibudilast) and TMZ combination treatment was safe and well-tolerated, and no unexpected adverse effects were reported.

The highlights of the presentation are as follows:

Phase II clinical trial and immunohistochemistry study

- The trial enrolled a total of 62 patients, including 36 newly diagnosed GBM (new GBM) patients and 26 recurrent GBM patients
    - Study participants' mean age at screening was 58.9 years old for new GBM and 59.6 years old for recurrent GBM
    - 39% of patients were female in both groups
    - 94% of new GBM patients and 100% of recurrent GBM patients were Caucasian
- All of the subjects received TMZ and MN-166 (ibudilast) treatment
- Progression-Free Survival at 6 months (PFS6) was 44% for new GBM and 31% for recurrent GBM
- Immunohistochemistry evaluation was performed for the patients whose pre-treatment tumor tissue samples were available from resected tumors at the initial surgery or biopsy to evaluate MIF (macrophage migration inhibitory factor), pERK, Ki67, CD3, CD11b, and CD74
    - CD3 expression was a good predictor for tumor progression at five months in recurrent glioblastoma subjects treated with MN-166 (ibudilast) and TMZ as subjects with progression had higher CD3 tumor infiltration than subjects with no progression ($p<0.05$)

Preclinical GBM model studies

- C57BL/6 mice were intracranially injected with SB28 tumor cells at 4 weeks of life and then treated with either isotype control, vehicle control, MN-166 (ibudilast), anti-PD1, anti-PDL1 or a combination therapy
    - Median survival was 17 days for the vehicle and 28 days for the anti-PD1 inhibitor treatment alone. The addition of MN-166 (ibudilast) to the anti-PD1 inhibitor treatment significantly extended survival to a median of 66 days ($p<0.001$) for the combination therapy.
    - Median survival was 18 days for the vehicle and 26 days for the anti-PD-L1 inhibitor treatment alone. The addition of MN-166 (ibudilast) to the anti-PD-L1 inhibitor treatment significantly extended survival to a median of 34 days ($p<0.05$) for the combination therapy.

Kazuko Matsuda, M.D., Ph.D., M.P.H., Chief Medical Officer of MediciNova, Inc., commented, "We are very pleased to report the positive safety and efficacy results from the first GBM clinical trial of MN-166. GBM's rapid progression and resistance to therapy poses a serious challenge to the medical community. Evaluation of MN-166 (ibudilast) as an adjuvant therapy with TMZ in GBM patients was generally safe and well tolerated. For the PFS6 primary efficacy endpoint, recurrent GBM patients showed a higher PFS6 rate compared to most historical studies. Moreover, the preclinical studies presented at this meeting support our postulation that adding MN-166 (ibudilast) to existing therapies, e.g., TMZ, anti-PD1 or anti-PD-L1, improves survival more than the individual therapies alone. We are excited by the findings presented by our esteemed collaborators and look forward to completing the full data analysis from the GBM clinical trial. We are eager to evaluate MN-166 (ibudilast) in combination with anti-PD1 and anti-PD-L1 therapies in a future clinical trial. MediciNova is grateful to the patients and families for their invaluable participation in our trial."

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, 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).

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, 2022 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

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