MediciNova Announces New Data Regarding MN-166 (ibudilast) in Glioblastoma Tumor Tissue Analysis Presented at the 20th Annual World Congress of Society for Brain Mapping and Therapeutics

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LA JOLLA, Calif., Feb. 20, 2023 (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 MediciNova's research collaborator, Justin Lathia, PhD, Scientific Director of the Rose Ella Burkhardt Brain Tumor and Neuro-Oncology Center at Cleveland Clinic and Professor, Department of Molecular Medicine at Cleveland Clinic Lerner College of Medicine of Case Western Reserve University, Professor and Vice Chair in the Department of Cardiovascular & Metabolic Sciences at the Lerner Research Institute, Cleveland Clinic presented new data regarding tumor tissue analysis and clinical outcome from a glioblastoma clinical trial (protocol no. MN-166-GBM-1201; NCT03782415) at the 20th Annual World Congress of SBMT (Society for Brain Mapping and Therapeutics) held on February 16 - 19, 2023, in Los Angeles, CA.

This tumor analysis study was a collaborative effort between MediciNova, Dr. Patrick Wen (Dana- Farber Cancer Institute), and Dr. Lathia (Cleveland Clinic Foundation). MN-166-GBM-1201 is an ongoing Phase 1/2 study targeting recurrent and newly diagnosed glioblastoma being conducted at Dana-Farber Cancer Institute under Principal Investigator: Dr. Wen, Director at Center for Neuro-Oncology Dana-Farber Cancer Institute, Professor of Neurology, Harvard Medical School.

The highlights of Dr. Lathia 's presentation are as follows:

- Tumor tissues were analyzed to determine potential predictors of treatment response to MN-166 (ibudilast) and temozolomide (TMZ) combination treatment.
- Pre-treatment tumor tissues were obtained from the resected tumors at the initial surgery or biopsy of trial participants (Part 1) diagnosed with recurrent glioblastoma.
- Immunohistochemistry was performed on resected tumor tissue to evaluate MIF (macrophage migration inhibitory factor), pERK, Ki67, CD3, CD11b, and CD74. A masked researcher calculated the score for each protein per patient.
- Study participants were divided into two groups: non-responders (disease progression within five months after receiving MN-166 and TMZ) and responders (no disease progression for five months after receiving MN-166 and TMZ).
- Responders had a lower percentage of CD3+ T cells than non-responders ($p<0.05$). Additionally, CD74 expression was also lower in the responders and this trended towards significance ($p=0.06$).
- CD3 expression was the best predictor for tumor progression for five months in recurrent glioblastoma patients treated with MN-166 and TMZ.

Dr. Lathia commented "Previously we reported that MN-166, as a brain-penetrant MIF-CD74 interaction inhibitor, reduced myeloid-derived suppressor cells (MDSC) generation and reversed their T cell suppressive capacity in vitro. Additionally, MN-166 reduced monocytic-MDSCs and increased CD8+ T cell number and function in the tumor microenvironment in murine model study. These new findings from clinical tumor tissue analysis may be explained by treatment with MN-166 resulting in increased CD3+ infiltration into tumor tissue in the patients who began with low CD3+ due to high MDSCs. This will need to be confirmed in a larger cohort."

Kazuko Matsuda, M.D. Ph. D, M.P.H., Chief Medical Officer, MediciNova, Inc., commented, "GBM is the most common primary malignant brain tumor and has a poor prognosis. It is a highly immunosuppressive tumor and there are limitations to the extent of a safe immune response in the central nervous system. We are excited by the findings presented by Dr. Lathia. Recently, we have completed study enrollment with MN-166-GBM-1201 study and look forward to the upcoming data analysis with more tissue samples."

About Glioblastoma

According to the American Association of Neurological Surgeons, glioblastoma is an aggressive brain cancer that often results in death during the first 15 months after diagnosis. Glioblastoma develops from glial cells (astrocytes and oligodendrocytes), grows rapidly, and commonly spreads into nearby brain tissue. Glioblastoma is classified as Grade IV, the highest grade, in the World Health Organization (WHO) brain tumor grading system. The American Brain Tumor Association reports that glioblastoma represents about 15% of all primary brain tumors and approximately 10,000 cases of glioblastoma are diagnosed each year in the U.S. Despite decades of advancements in neuroimaging, neurosurgery, chemotherapy and radiation therapy, only modest improvements have been achieved and the prognosis has not improved for individuals diagnosed with glioblastoma. Median survival is about 11-15 months for adults with more aggressive glioblastoma (IDH-wildtype) who receive standard treatment of surgery, temozolomide, and radiation therapy.

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, 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 glioblastoma 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.

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