MediciNova Announces Data from Phase 1b/2a Clinical Trial of MN-166 (ibudilast) in Glioblastoma Patients at the American Society of Clinical Oncology (ASCO) Annual Meeting 2024

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LA JOLLA, Calif., June 03, 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 MediciNova's collaborator, Gilbert Youssef, M.D. at Harvard Medical School, Attending Physician, Center for Neuro-Oncology at Dana-Farber Cancer Institute and Brigham and Women's Hospital, presented new data and results of a Phase 1b/2a Clinical Trial of MN-166 (ibudilast) in Glioblastoma (GBM) at the American Society of Clinical Oncology (ASCO) Annual meeting 2024 held May 31- June 4th in Chicago, IL.

The highlights of presentation entitled **"*Phase 1b/2a study evaluating the combination of MN-166 (ibudilast) and temozolomide (TMZ) in patients with newly diagnosed and recurrent glioblastoma (GBM*) (Abstract # 2016)" are as follows:

- The clinical study enrolled a total of 62 patients, including 36 with newly diagnosed GBM patients and 26 with recurrent GBM.
- The primary endpoints were safety and tolerability of MN-166 and TMZ combination treatment and the efficacy of combination treatment.
- The recommended Phase 2-dose (R2PD) of MN-166 is 50 mg BID.
- The combination of Temozolomide (TMZ) and MN-166 was safe and well tolerated. No unexpected adverse effects were observed in both new GBM and recurrent GBM patients. Most reported adverse events were Lymphopenia, Leukopenia, Thrombocytopenia and Neutropenia.
- Progression Free Survival at 6 months (PFS6) was 44% (new GBM) and 31% (recurrent GBM), respectively. PFS6 in recurrent GBM was higher than historical control.
- Median PFS was 8.7 months in new GBM and 2.4 months in recurrent GBM. Median Overall Survival (OS) was 21 months in new GBM and 8.6 months in recurrent GBM. Neither were higher than historical data.
- Immunohistochemistry evaluation was performed for the patients whose pre-treatment tumor tissue samples were available from resected tumors at initial surgery or biopsy to evaluate MIF (macrophage migration inhibitory factor), pERK, Ki67, CD3, CD11b, and CD74
    - The intra-tumoral CD3 expression was significantly higher in the patients had disease progression within 5 months of treatment initiation compared to patients that had no disease progression over 5 months, whereas the expression of MIF, CD74 (MIF receptor), Ki67 (proliferation index), and CD11b (marker expressed on myeloid-derived suppressor cells and macrophages, among other cell types) were not different between these 2 subgroups of patients.
- Preclinical data has shown improved survival with the combination of Ibudilast and PD-1 or PD-L1 antibody therapy compared to treatment with ibudilast alone or PD-1/PD-L1 antibody alone, suggesting a potential promising therapeutic benefit of this combination.

Kazuko Matsuda, M.D., Ph.D., M.P.H., Chief Medical Officer of MediciNova, Inc., commented, "First, we wish to express our sincere thanks to the study participants, their familys, the investigators, and their staff for their dedication and courage to conduct and volunteer for this trial. We are very pleased to have the opportunity to present our positive safety and efficacy results from the clinical trial of MN-166 in the treatment of GBM at the most prestigious clinical oncology conference. 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 data from 2 different research groups presented at this meeting support our postulation that adding MN-166 (ibudilast) to existing immunotherapy, i.e. anti-PD1 or anti-PD-L1, improves survival more than the individual therapies alone. We are eager to evaluate MN-166 (ibudilast) in combination with anti-PD1 and anti-PD-L1 therapies in a future clinical 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 also 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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