MediciNova Announces Initiation of Enrollment in a Clinical Trial of MN-166 (ibudilast) in Glioblastoma

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LA JOLLA, Calif., Jan. 08, 2019 (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 the first glioblastoma patient has enrolled in the clinical trial of MN-166 (ibudilast) in combination with temozolomide (TMZ, Temodar®) for the treatment of recurrent glioblastoma (GBM). The principal investigators are Patrick Y. Wen, M.D., Professor of Neurology, Harvard Medical School and Director, Neuro-Oncology Division at the Dana-Farber Cancer Institute (DFCI) in Boston, and Kerrie McDonald, Ph.D., Associate Professor and Head of Biomarkers and Translational Research at the Lowy Cancer Research Centre, University of New South Wales, Australia.

The scientific rationale for this clinical trial is based on positive results from preclinical studies conducted by Dr. McDonald and her team. MN-166 (Ibudilast) and temozolomide (TMZ) combination treatment significantly increased GBM cell apoptosis and cell cycle arrest in an in-vitro study. Combination treatment of MN-166 (ibudilast) with TMZ resulted in significantly extended survival times compared to TMZ monotherapy in a GBM animal model study with complete tumor regression observed in two out of 16 mice. This is the first clinical trial to evaluate the safety, tolerability and preliminary efficacy of MN-166 (ibudilast) in combination with temozolomide for the treatment of recurrent GBM.

Patrick Y. Wen, M.D., principal investigator, commented, “We are very excited to study ibudilast with TMZ combination treatment as we believe ibudilast’s mechanisms of action and good penetration of the blood-brain barrier could benefit patients with recurrent GBM.”

Kerrie McDonald, Ph.D., Associate Professor, University of New South Wales, Australia, commented, “Earlier studies indicate that macrophage migration inhibitory factor (MIF) and phosphodiesterase (PDE)-4 may factor in proliferation of GBM tumors. MIF was found to be highly expressed within GBM cells, and especially around necrotic areas and in close proximity to blood vessels. Ibudilast in combination with TMZ resulted in significant blockage of MIF expression, increased apoptosis, and longer survival in vivo.”

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased that enrollment has commenced for this trial at Dana-Farber Cancer Institute, one of the most highly rated cancer treatment institutions in the U.S. We believe MN-166 offers a novel approach to treating GBM, a highly lethal form of cancer that develops from glial cells.”

About the Clinical Trial

This Phase 1/2 clinical trial is divided into a dose-escalation phase (Part 1) followed by a fixed-dose phase (Part 2). A total of 15-18 adult subjects are planned to be enrolled in Part 1 and approximately 32 subjects are planned to be enrolled in Part 2. Part 1 will evaluate the safety and tolerability of MN-166 (ibudilast) when given in combination with TMZ, and determine the dose of MN-166 (ibudilast) to be used in Part 2 of the study. Part 2 will evaluate the efficacy of MN-166 (ibudilast) and temozolomide combination treatment in patients with recurrent GBM as measured by the proportion of patients who are progression-free at 6 months. Other outcome measures include the evaluation of overall survival, response rate, and median six-month progression-free survival.

About Glioblastoma

According to the American Association of Neurological Surgeons, GBM is a devastating brain cancer that typically results in death in the first 15 months after diagnosis. GBM develops from glial cells (astrocytes and oligodendrocytes) and rapidly grows and commonly spreads into nearby brain tissue. GBM 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 GBM represents 15% of all brain tumors and 56% of all gliomas and has the highest number of cases of all malignant tumors, with an estimated 12,760 new cases predicted for 2018. 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 GBM. Median survival is 14.6 months and two-year survival is 30%. Approximately 5% of GBM patients survive longer than 36 months.

About MN-166 (ibudilast)
MN-166 (ibudilast) is a first-in-class, orally bioavailable, small molecule macrophage migration inhibitory factor (MIF) inhibitor and phosphodiesterase (PDE) -4 and -10 inhibitor that suppresses pro-inflammatory cytokines and promotes neurotrophic factors. It attenuates activated glial cells, which play a major role in certain neurological conditions. MN-166 (ibudilast)'s anti-neuroinflammatory and neuroprotective actions have been demonstrated in preclinical and clinical studies, which provide the rationale for treatment of progressive multiple sclerosis (MS) and other neurological diseases such as amyotrophic lateral sclerosis (ALS), substance abuse/addiction and glioblastoma (GBM). MediciNova is developing MN-166 for progressive MS and other neurological conditions such as ALS, substance abuse/addiction, chemotherapy-induced neuropathy, and glioblastoma. MediciNova has a portfolio of patents which cover the use of MN-166 (ibudilast) to treat various diseases including progressive MS, ALS, and drug addiction.

About MediciNova
MediciNova, Inc. is a publicly-traded biopharmaceutical company founded upon developing novel, small-molecule therapeutics for the treatment of diseases with unmet medical needs with a primary commercial focus on the U.S. market. MediciNova's current strategy is to focus on MN-166 (ibudilast) for neurological disorders such as progressive multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), substance dependence (e.g., alcohol use disorder, methamphetamine dependence, opioid dependence) and glioblastoma (GBM), and MN-001 (tipelukast) for fibrotic diseases such as nonalcoholic steatohepatitis (NASH) and idiopathic pulmonary fibrosis (IPF). MediciNova’s pipeline also includes MN-221 (bedoradrine) and MN-029 (denibulin). For more information on MediciNova, Inc., please visit www.medicinova.com.

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-221, MN-001, 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-221, MN-001, 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, 2017 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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