MediciNova Announces Positive Preclinical Results Regarding MN-166 (ibudilast) in Glioblastoma (GBM) Published in Frontiers in Immunology

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LA JOLLA, Calif., June 25, 2020 (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 positive preclinical findings published in *Frontiers in Immunology* regarding the prospect of MN-166 (ibudilast) as an adjunct treatment for glioblastoma.

The publication, entitled “Glioblastoma myeloid-derived suppressor cell subsets express differential macrophage migration inhibitory factor receptor profiles that can be targeted to reduce immune suppression”, was a collaborative effort between MediciNova and the Cleveland Clinic, led by Tyler Alban (doctoral candidate) and Dr. Justin Lathia, Co-Director of the Brain Tumor Research and Therapeutic Development Center of Excellence at the Lerner Research Institute, Cleveland Clinic, and Associate Professor, Department of Molecular Medicine at Case Western Reserve University. Dr. Lathia, Dr. Michael Vogelbaum (previously at the Cleveland Clinic, now at Moffitt Cancer Center in Tampa, FL) and colleagues previously reported on findings that GBM patients had higher levels of immune suppressive myeloid-derived suppressor cells (MDSCs) in the tumor microenvironment and they tended to be resistant to and dependent on macrophage migration inhibitory factor (MIF). In this research publication, in collaboration with Dr. Richard Bucala (Yale University), they report the monocytic subset of MDSCs (M-MDSCs) expressed high levels of the MIF cognate receptor CD74 in the tumor microenvironment. This finding is meaningful in that targeting M-MDSCs with ibudilast, a brain penetrant MIF-CD74 interaction inhibitor, resulted in decreased MDSC function and enhanced CD8 T cell activity in the tumor microenvironment. They note that clinical trial results to date suggest that treatment with an immune stimulatory therapy alone is not effective in treating GBM and hypothesized that better clinical outcomes will be seen when an immune stimulatory therapy is combined with ibudilast, which has been shown to reverse tumor-induced immune suppression.

Dr. Justin Lathia commented, “We found that the receptor CD74 may play a greater role in GBM MDSC biology because the subset of MDSCs primarily found in the tumor microenvironment were M-MDSCs, which predominantly express CD74 as a MIF receptor. These findings are significant for treating patients diagnosed with GBM. Among multiple anti-MIF agents we tested, ibudilast was most potent with reducing M-MDSCs. Ibudilast readily crosses the blood-brain barrier, an advantage over other agents, and has a strong safety profile. Our hope is that combining ibudilast and immune stimulatory therapy will translate to decreased disease progression in clinical trials.”

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We have an ongoing clinical trial evaluating MN-166 in combination with temozolomide for the treatment of GBM at the Dana-Farber Cancer Institute, Harvard Medical School. Recently, we expanded our target population to include patients with either recurrent or newly diagnosed GBM. A recently published GBM animal model study showed that median survival was longer in the group treated with MN-166 plus temozolomide than in the group treated with temozolomide alone. The new findings reported by Dr. Lathia and his colleagues may lead to the use of MN-166 as combination therapy with immune stimulatory treatment and may offer a new treatment option to patients with GBM, one of the most serious refractory cancers.”

About Glioblastoma

According to the American Association of Neurological Surgeons, glioblastoma is an aggressive brain cancer that often results in death within 15 months of 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 approximately 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 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. Our earlier human studies demonstrated significant reductions of serum MIF level after treatment with MN-166 (ibudilast). It also 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 amyotrophic lateral sclerosis (ALS), progressive multiple sclerosis (MS) and other neurological diseases such as glioblastoma (GBM), and substance abuse/addiction. MediciNova is developing MN-166 for ALS, progressive MS and other neurological conditions such as degenerative cervical myelopathy (DCM), glioblastoma, substance abuse/addiction, and chemotherapy-induced peripheral neuropathy. MediciNova has a portfolio of patents which covers the use of MN-166 (ibudilast) to treat various diseases including ALS, progressive MS, 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), degenerative cervical myelopathy (DCM), 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-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, 2019 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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