MediciNova Receives Notice of Allowance for Second Patent Covering MN-166 (ibudilast) for the Treatment of Glioblastoma

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LA JOLLA, Calif., April 20, 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 that it has received a Notice of Allowance from the U.S. Patent and Trademark Office for a pending patent application which covers MN-166 (ibudilast) for the treatment of glioblastoma. This new patent has improved therapeutic claims compared to the first patent which covers MN-166 (ibudilast) for the treatment of glioblastoma, which was granted last year, and has a later expiration date than the first patent.

Once issued, the patent maturing from this allowed patent application is expected to expire no earlier than February 2039. The allowed claims cover a method of treating a patient diagnosed with glioblastoma or recurrent glioblastoma, wherein the patient expresses methylated MGMT (O6-methylguanine-DNA methyltransferase), using MN-166 (ibudilast) in combination with one or more other therapeutic agents including temozolomide (TMZ), carmustine, bevacizumab, procarbazine, hydroxyurea, irinotecan, lomustine, nimotuzumab, sirolimus, mipsagargin, cabozantinib, onartuzumab, patupilone (epothilone B), and recombinant oncolytic poliovirus (PVS-RIPO). The allowed claims cover a wide range of doses of MN-166 (ibudilast) during an optionally repeating dosing cycle. The allowed claims also cover different types of glioblastoma including classical glioblastoma, proneural glioblastoma, mesenchymal glioblastoma, and neural glioblastoma.

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased to receive notice that this new patent will be granted as it offers better coverage than our first patent covering glioblastoma. We believe it could substantially increase the potential value of MN-166 as we have an ongoing clinical trial of MN-166 in combination with temozolomide for the treatment of recurrent glioblastoma at the Dana-Farber Cancer Institute, Harvard Medical School. Results of the glioblastoma animal model study showed that median survival was longer in the group that received combination treatment with MN-166 plus temozolomide compared to the group that received the standard treatment of temozolomide alone, and this data was presented at the American Society of Clinical Oncology (ASCO) annual meeting. Encouragingly, the FDA granted orphan-drug designation to MN-166 as adjunctive therapy to temozolomide for the treatment of glioblastoma based on this data."

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 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.

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