MediciNova Receives Issue Notification for a New Patent Covering MN-166 (ibudilast) for the Treatment of Glioblastoma

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LA JOLLA, Calif., Sept. 14, 2022 (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 an Issue Notification from the U.S. Patent and Trademark Office for a new patent which covers MN-166 (ibudilast) for the treatment of glioblastoma.

This new patent 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 unmethylated MGMT, 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) as well as the other therapeutic agents. The allowed claims also cover different types of glioblastoma including classical glioblastoma, proneural glioblastoma, mesenchymal glioblastoma, and neural glioblastoma.

Kazuko Matsuda, MD, PhD, MPH, Chief Medical Officer of MediciNova, Inc. commented, “We are very pleased to receive the issue notification for this new patent as it offers additional coverage compared to our other two patents covering glioblastoma. 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 our 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 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, 2021 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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