MediciNova, in Collaboration with the University of Sydney and the Australasian Gastro-Intestinal Trials Group, Announces Plans for a Multi-center, Phase 2b Study to Evaluate MN-166 (ibudilast) in Chemotherapy-Induced Peripheral Neuropathy

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LA JOLLA, Calif., Oct. 22, 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 plans to initiate a multi-center, placebo-controlled, randomized Phase 2b trial to evaluate MN-166 (ibudilast) in chemotherapy-induced peripheral neuropathy (CIPN).

The clinical trial is a collaborative effort between MediciNova, the University of Sydney, and the Australasian Gastro-Intestinal Trials Group (AGITG). Dr. Janette Vardy, Professor of Cancer Medicine, University of Sydney in Australia, will be the lead principal investigator. The proposed clinical trial will evaluate MN-166 (ibudilast) as a potential treatment to reduce acute neurotoxicity severity and CIPN in patients with metastatic colorectal cancer. AGITG will provide funding for this study and MediciNova will provide study drug and regulatory support.

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc. commented, “We are excited to collaborate with Dr. Vardy on this grant-funded study to further explore the potential of MN-166 as a pharmacotherapy for CIPN. As we recently reported, our first clinical trial in CIPN showed that half of participants reported improved symptoms in the acute period and showed improved neurological parameters on clinical assessment with ibudilast treatment. There is a large unmet medical need for patients with this disorder.”

Dr. Janette Vardy, the Principal Investigator for this study, commented, “The findings from our initial study were encouraging, and with the support of AGITG and MediciNova, we plan to explore further the potential clinical utility of ibudilast in a larger sample of patients who experience oxaliplatin-induced acute neurotoxicity and chronic CIPN.”

About the Chemotherapy-induced Peripheral Neuropathy Trial

This study is a multi-center, randomized, double-blind, placebo-controlled Phase 2b trial to determine whether MN-166 (ibudilast) can decrease acute neurotoxicity symptoms and CIPN, and to determine whether ibudilast treatment results in fewer neurotoxicity-induced dose reductions in patients with metastatic colorectal cancer receiving oxaliplatin up to six months. We plan to enroll a total 100 patients in a 1:1 (ibudilast:placebo) ratio. Treatment (MN-166 (ibudilast) 60 mg/day or matching placebo) will commence two days prior to the first cycle of oxaliplatin chemotherapy and will continue for the duration of the oxaliplatin chemotherapy.

About Chemotherapy-induced Peripheral Neuropathy

Peripheral neuropathy is a set of symptoms caused by damage to the nerves that are outside of the brain and spinal cord. These distant nerves are called peripheral nerves. Some of the chemotherapy and other drugs used to treat cancer can damage peripheral nerves that carry sensations to the hands and feet. This damage results in chemotherapy-induced peripheral neuropathy (CIPN) and is a common side effect of cancer chemotherapy. Most commonly, people complain of “pins and needles” in their toes and fingers. CIPN may affect cancer outcomes due to reductions in chemotherapy dosing and/or premature treatment discontinuation and have a profound impact on quality of life and survivorship. According to a meta-analysis which included more than 4,000 patients, CIPN prevalence was 68% when measured in the first month after chemotherapy, 60% at 3 months, and 30% at 6 months or more (Seretny et al., 2014). Long-term neurotoxicity is an important issue for the growing number of cancer survivors, with the highest number of affected patients having been treated for breast and/or colon cancer.

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, as well as prevention of acute respiratory distress syndrome (ARDS) caused by COVID-19. 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 BC-PIV SARS-COV-2 vaccine for COVID-19, 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), as well as prevention of acute respiratory distress syndrome (ARDS) caused by COVID-19, 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 BC-PIV SARS-COV-2 vaccine, 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 BC-PIV SARS-COV-2 vaccine, 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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