MediciNova Announces Collaboration with the University of Sydney Concord Cancer Centre to Evaluate MN-166 (ibudilast) in Chemotherapy-Induced Peripheral Neuropathy

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LA JOLLA, Calif., March 28, 2018 (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 pilot study to evaluate MN-166 (ibudilast) in chemotherapy-induced peripheral neuropathy.

The clinical trial is a collaborative effort between MediciNova, Inc. and Dr. Janette Vardy, Professor of Cancer Medicine, University of Sydney Concord Cancer Centre in Australia. The proposed clinical trial will evaluate MN-166 (ibudilast) as a potential treatment for individuals with chemotherapy-induced peripheral neuropathy. A Concord Cancer Centre Research grant will provide funding for this study and MediciNova will provide study drug.

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 explore the potential of MN-166 as a pharmacotherapy for chemotherapy-induced peripheral neuropathy. There is a large unmet medical need for patients with this disorder.”

Dr. Janette Vardy, the Principal Investigator for this study, commented, “This is an exciting new project and we are enthusiastic to partner with MediciNova to evaluate MN-166 in chemotherapy-induced peripheral neuropathy patients. As chemotherapy-induced peripheral neuropathy is believed to be caused by glial activation, we believe ibudilast’s ability to reduce glial activation could be beneficial in treating this common disorder following chemotherapy.”

About the Trial

This is a prospective, open-label, sequential cross-over pilot study assessing acute neurotoxicity, chemotherapy-induced peripheral neuropathy, and drug interactions of ibudilast in 20 patients with metastatic gastrointestinal cancer (colorectal cancer and upper gastrointestinal cancers) who are receiving oxaliplatin.

The study aims to determine: 1) whether ibudilast can prevent the development of acute neurotoxicity in patients receiving oxaliplatin for the treatment of metastatic gastrointestinal cancer; 2) the effect of ibudilast co-administration, if any, on the pharmacokinetics of oxaliplatin and fluorouracil; and 3) whether ibudilast might decrease the severity of chemotherapy-induced peripheral neuropathy.

Participants will undertake pharmacokinetics assay and neurotoxicity assessment for a cycle of their usual chemotherapy, followed by identical assessments the following cycle with concurrent administration of oral ibudilast 30 mg twice daily. Assessments for chemotherapy-induced peripheral neuropathy will occur at baseline, day 3 of chemotherapy, end of each cycle, and 3 months after baseline, and will be compared to determine a clinical benefit, as well as safety and medication adherence.

About Concord Cancer Centre

Concord Cancer Centre, part of the University of Sydney, is based at Concord Repatriation General Hospital, a major tertiary hospital in Sydney Local Health District in Australia. Concord Repatriation General Hospital is one of the best cancer treatment and research facilities in New South Wales.

About Chemotherapy-Induced Peripheral Neuropathy

Peripheral neuropathy is a set of symptoms caused by damage to the nerves that are away from 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 (“Incidence, prevalence, and predictors of chemotherapy-induced peripheral neuropathy: A systematic review and meta-analysis,” Seretny M 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 Oxaliplatin-induced Peripheral Neuropathy

Oxaliplatin is shown to improve survival of patients with colorectal cancer and other gastrointestinal cancers. The neurotoxicity seen with oxaliplatin treatment, in the form of the acute and chronic syndrome, ranks among the most frequent non-hematological toxicity due to this treatment. The acute, transient neurotoxicity occurs in nearly all patients, is rapid in onset, and occurs during or within hours of the oxaliplatin infusion. The dose-limiting, cumulative sensory neurotoxicity may be severe enough to limit patients from performing their activities of daily living. A proposed mechanism for this process is central and dorsal root ganglion neuroinflammation caused by oxaliplatin.

About MN-166 (ibudilast)

MN-166 (ibudilast) has been marketed in Japan and Korea since 1989 to treat post-stroke complications and bronchial asthma. MN-166 (ibudilast) is a first-in-class, orally bioavailable, small molecule phosphodiesterase (PDE) -4 and -10 inhibitor and a macrophage migration inhibitory factor (MIF) inhibitor that suppresses pro-inflammatory cytokines and promotes neurotrophic factors. It attenuates activated glia cells, which play a major role in certain neurological conditions. Ibudilast's anti-neuroinflammatory and neuroprotective actions have been demonstrated in preclinical and clinical study results and provide the rationale for its therapeutic utility in substance use disorders, neurodegenerative diseases (e.g., ALS and progressive

MS), and chronic neuropathic pain. MediciNova is developing MN-166 for various neurological conditions such as progressive MS, ALS and substance abuse/addiction.

About MediciNova

MediciNova, Inc. is a publicly-traded biopharmaceutical company founded upon acquiring and developing novel, small-molecule therapeutics for the treatment of diseases with unmet medical needs with a commercial focus on the U.S. market. MediciNova's current strategy is to focus on MN-166 (ibudilast) for neurological disorders such as progressive MS, ALS and substance dependence (*e.g.*, alcohol use disorder, methamphetamine dependence and opioid dependence), 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) for the treatment of acute exacerbations of asthma and MN-029 (denibulin) for solid tumor cancers. MediciNova is engaged in strategic partnering and other potential funding discussions to support further development of its programs. 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 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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