MediciNova Announces Positive Clinical Results Regarding MN-166 (ibudilast) for Prevention of Chemotherapy-induced Peripheral Neuropathy Published in Cancer Chemotherapy and Pharmacology

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LA JOLLA, Calif., Sept. 24, 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 clinical findings published in *Cancer Chemotherapy and Pharmacology* regarding MN-166 (ibudilast) as a treatment for prevention of chemotherapy-induced peripheral neuropathy (CIPN).

The publication, entitled "**Ibudilast for prevention of oxaliplatin-induced acute neurotoxicity: a pilot study assessing preliminary efficacy, tolerability, and pharmacokinetic interactions in patients with metastatic gastrointestinal cancer**", is the result of a collaborative effort between MediciNova and Dr. Janette Vardy, Professor of Cancer Medicine, University of Sydney Concord Cancer Centre in Australia. The authors report that co-administration of MN-166 (ibudilast) with oxaliplatin resulted in improvement or stabilization of oxaliplatin-induced neurotoxicity in the majority of participants treated with oxaliplatin.

This prospective, open-label, sequential crossover study was conducted to assess whether MN-166 (ibudilast) can reduce acute peripheral neuropathy symptoms in patients with metastatic upper gastrointestinal or colorectal cancer. A total 16 patients consented, and 14 patients completed two cycles of oxaliplatin-containing chemotherapy, one cycle with conventional chemotherapy (Cycle A) and one cycle of chemotherapy with concurrent MN-166 treatment (Cycle B). As a cross-over design, each participant acted as their own control. Participants underwent a number of assessments for neurotoxicity on Day 3 of each cycle, and at the completion of each cycle, including the Oxaliplatin-Specific Neurotoxicity Scale (OSNS), the Total Neuropathy Score Clinical (TNSc), the Functional Assessment of Cancer Therapy/Gynaecologic Oncology Group—Neurotoxicity (FACT/GOG-Ntx13), and the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) neuropathy subscale.

Major findings from the publication are as follows:

- Across all neurotoxicity measures, a majority of participants experienced either an improvement or no worsening of neurotoxicity with MN-166 (ibudilast) treatment
    - According to OSNS assessments, 12 out of 14 participants reported acute neurotoxicity (Grade 1 or 2) in both cycles. Of those, 10 out of 12 participants were unchanged and 2 participants had improved symptoms from Grade 2 to Grade 1 with MN-166 (ibudilast) co-treatment.
    - According to score changes with FACT/GOG-Ntx13, TNSc and NCI-CTCAE, a majority of participants had no worsening of scores at the Day 3 and end of cycle time-points for Cycle B compared to Cycle A.
- Pharmacokinetic analysis indicated no effect of MN-166 (ibudilast) on systemic exposure of oxaliplatin.

Yuichi Iwaki, M.D., Ph.D., President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased to report positive results from this study. Acute neurotoxicity, which predicts chronic CIPN, usually recurs with oxaliplatin chemotherapy and in most cases, patients experience worsening of neurotoxicity symptoms with continued chemotherapy. What makes this remarkable is that half of participants reported improved symptoms in the acute period and showed improved neurological parameters on clinical assessment with ibudilast treatment."

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 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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