MediciNova Initiates Sheep Study under Partnership with BARDA to Develop MN-166 (ibudilast) as a Medical Countermeasure Against Chlorine Gas-induced Lung Injury

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LA JOLLA, Calif., June 07, 2021 (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 it has initiated a sheep study to investigate MN-166 (ibudilast) in an ovine model of chlorine-induced acute lung injury. Following treatment of the sheep with MN-166 (ibudilast) or control, the study will evaluate pulmonary function, lung injury and edema formation, cardiopulmonary hemodynamics, and systemic vascular permeability.

MediciNova has partnered with the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, to repurpose MN-166 (ibudilast) as a potential medical countermeasure (MCM) against chlorine gas-induced lung damage such as acute respiratory distress syndrome (ARDS) and acute lung injury (ALI).

Federico Gaeta, Ph.D., Chief Scientific Officer of MediciNova, Inc., commented, “We are pleased to work with BARDA to initiate the first animal model study to evaluate MN-166 as a potential rapidly-administered treatment for patients exposed to chemical agents such as chlorine. Under the FDA Animal Rule, development of medical countermeasures (MCMs) does not require human clinical trials to establish efficacy when these trials would not be ethical or feasible. FDA can grant approval of a drug for a MCM indication based on well-controlled animal studies, when the results of these studies establish that the drug is reasonably likely to produce clinical benefit in humans. MN-166 attenuated histological changes observed in an ARDS mouse model, including pulmonary edema in lung tissue, and protected against pulmonary injury by reducing cellular apoptosis in lung tissue. Considering that pulmonary edema is a hallmark feature of exposure to chlorine, MN-166 has the potential to improve health outcomes and save lives.”

This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50121C00022.

About MN-166
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 for glioblastoma, CIPN (chemotherapy-induced peripheral neuropathy), and substance use disorder. In addition, MN-166 (ibudilast) is being evaluated in patients with COVID-19 that are at risk for developing ARDS.

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 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 ARDS caused by COVID-19, and MN-001 (tipelukast) for fibrotic diseases such as nonalcoholic steatohepatitis (NASH) and idiopathic pulmonary fibrosis (IPF). 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 and MN-001. 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 and MN-001, and risks of raising sufficient capital when needed to fund MediciNova's operations and contribution to clinical development, risks and uncertainties inherent to the development of formulations as well as the initiation and conduct of clinical trials and animal studies, including the potential cost, expected timing and risks associated with clinical trials and animal studies 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 and animal

studies 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 animal studies 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 and animal studies or significant issues regarding the adequacy of clinical trial and animal study designs or the execution of clinical trials and animal studies, 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, 2020 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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