MediciNova to Conduct Mouse 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 28, 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 will conduct a mouse study to investigate the efficacy of MN-166 (ibudilast) in a murine model of chlorine-induced lung injury and lethality. After mice are exposed to chlorine gas and treated with MN-166 (ibudilast) or control, the study will evaluate survival, clinical outcomes, body weights, lung weights, and upper respiratory tract histopathology.

This mouse study and the sheep study announced recently are the result of a partnership between MediciNova and 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 reach agreement to conduct a study in BARDA’s validated mouse model of chlorine-induced pulmonary injury using higher challenge concentrations. This will be the second animal model study to evaluate MN-166 as a potential rapidly administered treatment for patients exposed to chemical agents such as chlorine. We will evaluate survival rate, clinical status, and lung histological changes compared to control mice. In a previous ARDS mouse model study, MN-166 attenuated histological changes including pulmonary edema in lung tissue and protected against pulmonary injury by attenuating the secretion of inflammatory cytokines and 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 is federally funded in part by 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 that are at risk for developing 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, patients at risk of developing acute respiratory distress syndrome (ARDS), and substance dependence. MN-001 (tipelukast) is being evaluated in a Phase 2 trial in idiopathic pulmonary fibrosis (IPF) and is in preparation for a second Phase 2 trial in nonalcoholic steatohepatitis (NASH). 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 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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