MediciNova Announces Presentation of Positive Findings on MN-001 (tipelukast) in Acute Liver Injury Model at The Liver Meeting Digital Experience™ 2020

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LA JOLLA, Calif., Nov. 12, 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 Principal Investigators Leila Gobejishvili, PhD and Craig McClain, MD at the University of Louisville School of Medicine presented positive results of the in-vitro and in-vivo studies that evaluated MN-001 (tipelukast, referred to as D46 in the presentation) for its anti-liver fibrotic effect in human hepatic stellate cells (HSCs) and in an acute liver injury model at the Liver Meeting Digital Experience™ 2020 (TLMdX™), the annual meeting of the American Association for the Study of Liver Diseases (AASLD).

The study was a collaborative effort between MediciNova, Inc., and Drs. Craig McClain and Leila Gobejishvili, University of Louisville Alcohol Research Center and Hepatobiology and Toxicology Centers of Biomedical Research Excellence (COBRE) at the University of Louisville in Louisville, Kentucky.

This study, funded by the National Institute of General Medical Sciences (NIGMS), one of the U.S. National Institutes of Health (NIH), sought to examine the pathogenic role of phosphodiesterase 4 (PDE4) in hepatic stellate cell (HSC) activation and TGFβ1 (transforming growth factor beta 1) signaling. Specifically, the studies evaluated the effect of PDE4 inhibitors on attenuating fibrotic processes with an emphasis on HSC activation.

The highlights of the presentation entitled "Modulation of TGFβ1 signaling by interaction of cAMP effectors and TGFβ1 type I receptor in hepatic stellate cells" are as follows:

MN-001 (D46) significantly attenuated

- TGFβ1 induced HSC activation
- TGFβ1 mediated increase in HSC motility and contractility by reducing myosin light chain (MLC) phosphorylation and Endothelin-1
- Fibrogenic signaling in a mouse acute carbon tetrachloride (CCl_4) induced liver injury model, specifically,
    - MN-001 (D46) decreased CCl_4-induced HSC activation demonstrated by reduced SMAD3 and alpha smooth muscle actin (αSMA) levels
    - MN-001 (D46) decreased CCl_4-induced liver αSMA, collagen 1a1 and lysyl oxidase 2 mRNA levels

Promoting cAMP signaling by using PDE4 inhibitors could be beneficial in attenuating the development of liver fibrosis.

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc. commented, “We are very pleased with the positive findings in an acute liver injury model study conducted by Dr. Gobejishvili and Dr. McClain. This is additional scientific evidence to support MN-001’s anti-fibrotic effects in the liver. We look forward to advancing to the next step to further investigate the potential of MN-001 in liver fibrosis.”

Dr. McClain, Professor of Medicine, Pharmacology and Toxicology, Chief of Research Affairs, Division of Gastroenterology, Hepatology and Nutrition, Director Clinical Trials Unit / Liver Research Program commented, “We are very excited to report positive data from our in-vitro and acute liver injury model study with MN-001 (D46). The attenuation of TGFβ1 signaling for HSC activation and the anti-fibrogenic effect in an acute liver injury model by MN-001 was very promising. We are looking forward to further collaboration with MediciNova.”

About MN-001

MN-001 (tipelukast) is a novel, orally bioavailable, small molecule compound thought to exert its effects through several mechanisms to produce its anti-inflammatory and anti-fibrotic activity in preclinical models, including leukotriene (LT) receptor antagonism, inhibition of phosphodiesterases (PDE) (mainly 3 and 4), and inhibition of 5-lipoxygenase (5-LO). The 5-LO/LT pathway has been postulated as a pathogenic factor in fibrosis development, and MN-001's inhibitory effect on 5-LO and the 5-LO/LT pathway is considered to be a novel approach to treat fibrosis. MN-001 has been shown to down-regulate expression of genes that promote fibrosis including LOXL2, Collagen Type 1 and TIMP-1. MN-001 has also been shown to down-regulate expression of genes that promote inflammation including CCR2 and MCP-1. In addition, histopathological data shows that MN-001 reduces fibrosis in multiple animal models.

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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