

# MediciNova Announces Positive Interim Safety Data From Clinical Trial of MN-166 (ibudilast) in ALS

April 21, 2015

LA JOLLA, Calif., April 21, 2015 (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), announced that Dr. Benjamin Rix Brooks, principal investigator, presented interim safety data from the ongoing clinical trial of MN-166 (ibudilast) in amyotrophic lateral sclerosis (ALS) today at the American Academy of Neurology (AAN) 67th Annual Meeting in Washington, DC. There were no safety or tolerability concerns in the MN-166 (ibudilast) treatment group compared with the placebo treatment group after three months of treatment.

An independent safety medical monitor completed an interim safety review of the first 21 subjects enrolled in the study. No cluster of adverse events was differentially present in subjects treated with MN-166 (ibudilast) compared with subjects treated with placebo. No clinically significant electrocardiogram abnormalities were noted in the MN-166 (ibudilast) treatment group or the placebo treatment group. Importantly, based on the findings from the interim safety review, the independent safety medical monitor recommended that the study continue as planned.

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased with the findings from the interim safety analysis, as we may now continue with the trial as planned. We look forward to completing enrollment and providing further updates as the study progresses."

### About the ALS Trial

The trial is a randomized, double-blind, placebo-controlled study which includes a six-month treatment period followed by a six-month open-label extension. The study is evaluating several efficacy endpoints including functional activity (ALSFRS-R), respiratory function, muscle strength, and non-invasive ventilation (NIV) utilization in addition to monitoring the safety and tolerability of MN-166 60 mg/day versus placebo when administered in combination with riluzole in subjects with ALS. The principal investigator of the study is Benjamin Rix Brooks, MD, Director, Carolinas Neuromuscular/ALS-MDA Center at Carolinas HealthCare System Neurosciences Institute in Charlotte, NC.

#### **About ALS**

Amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease, is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. The nerves lose the ability to trigger specific muscles, which causes the muscles to become weak. As a result, ALS affects voluntary movement and patients in the later stages of the disease may become totally paralyzed. Life expectancy of an ALS patient is usually 2-5 years. According to the ALS Association, there are approximately 30,000 ALS patients in the U.S. and approximately 5,600 people in the U.S. are diagnosed with ALS each year. Riluzole is the only pharmaceutical treatment approved for ALS, but it has limited efficacy.

## About MN-166 (ibudilast)

MN-166 (ibudilast) has been marketed in Japan and Korea since 1989 to treat post-stroke complications and bronchial asthma. MediciNova licensed MN-166 (ibudilast) from Kyorin Pharmaceutical for potential utility in relapse-remitting multiple sclerosis (RRMS). Intellectual property was additionally established or obtained by MediciNova in progressive MS and other neurological conditions. 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 neurodegenerative diseases (e.g. progressive MS and ALS), substance abuse/addiction and chronic neuropathic pain.

## **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. methamphetamine dependence, 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 <a href="https://www.medicinova.com">www.medicinova.com</a>.

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, 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, 2014 and its subsequent periodic reports on Forms 10-Q and 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.

CONTACT: INVESTOR CONTACT:

Geoff O'Brien
Vice President
MediciNova, Inc.
info@medicinova.com

MediciNova, Inc. Logo

MediciNova, Inc.