MediciNova Announces Interim Data from Clinical Trial of MN-166 (ibudilast) in ALS Presented at the American Academy of Neurology (AAN) 68th Annual Meeting in Vancouver, Canada

April 20, 2016

LA JOLLA, Calif., April 20, 2016 (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 principal investigator Dr. Benjamin Rix Brooks, Director, Carolinas HealthCare System's Neuromuscular/ALS-MDA Center, will present interim data today from MediciNova's ongoing clinical trial of MN-166 (ibudilast) in amyotrophic lateral sclerosis (ALS) at the American Academy of Neurology (AAN) 68th Annual Meeting at the Vancouver Convention Centre in Vancouver, BC, Canada. The interim analysis, which was performed by an independent statistician consultant, includes a total of 25 subjects without non-invasive ventilator support who completed the 6-month double-blind treatment period with complete spirometry (respiratory function test) data.

Major findings from the interim analysis include the following:

- The mean decline in the Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R) total score (the higher the score the more function is retained) from Baseline to Month 6 was 4.55 (0.76 per month) in the MN-166 group compared to 5.80 (0.97 per month) in the placebo group (a higher rate of decline indicates a greater worsening of disability).
- The lower decline in the ALSFRS-R total score in the MN-166 group was driven by lower declines in two ALSFRS-R subscores: the ALSFRS-R Bulbar score and the ALSFRS-R Arm score.
- The mean decline in the ALSFRS-R Bulbar score (which measures speech, salivation and swallowing ability) from Baseline to Month 6 was 0.90 (0.15 per month) in the MN-166 group compared to 1.80 (0.30 per month) in the placebo group.
- The mean decline in the ALSFRS-R Arm score (which measures handwriting, cutting foods/handling utensils, and dressing/hygiene ability) from Baseline to Month 6 was 1.50 (0.25 per month) in the MN-166 group compared to 2.40 (0.40 per month) in the placebo group.
- The mean decline in slow vital capacity (SVC), a measure of respiratory function, from Baseline to Month 6 was 10.93% (1.82% per month) in the MN-166 group compared to 12.71% (2.12% per month) in the placebo group.
- As this is the first study of MN-166 in ALS, there was no prior clinical data from which to base statistical powering assumptions. Hence, this study was not powered to detect statistical significance. This study does provide the necessary clinical data for powering assumptions for the next study of MN-166 in ALS.
- No cluster of adverse events was differentially present in MN-166 treatment and placebo treatment subjects.

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased with the positive interim data, particularly the ALSFRS-R data, which indicates that MN-166 has potential to slow disease progression in ALS patients. We believe the results for the bulbar subscore are particularly impressive as bulbar dysfunction accounts for many of the worst symptoms of ALS. The loss of the ability to swallow prevents eating and threatens survival. Loss of speech effectively results in a state of isolation."

About the ALS Trial

MediciNova, in collaboration with Dr. Benjamin Rix Brooks, Director, Carolinas HealthCare System Neuroscience Institute Neuromuscular/ALS-MDA Center, is currently evaluating MN-166 (ibudilast) in both early and advanced stage ALS patients. This ongoing 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 and muscle strength in subjects with ALS. The study is configured to enroll 60 ALS patients without NIV (Non-Invasive Ventilator) and an additional 60 ALS patients with NIV.

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 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-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 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, 2015 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.

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