U.S. Centers for Disease Control and Prevention (CDC) Supports Recruitment for MediciNova's Clinical Trial of MN-166 (Ibudilast) in ALS

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LA JOLLA, Calif., Oct. 23, 2014 (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 the U.S. CDC's National ALS Registry Research Committee has voted to approve support of patient recruitment for MediciNova's clinical trial of MN-166 (ibudilast) in amyotrophic lateral sclerosis (ALS). CDC has notified ALS patients who are registered with the CDC's National ALS Registry and who also met the inclusion criteria about the initiation of MediciNova's clinical trial of MN-166 (ibudilast) in ALS. Subject enrollment in this trial began in early October 2014.

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 will evaluate 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.

Dr. Benjamin Rix Brooks, Principal Investigator, commented, "We are extremely pleased to have the support of CDC in expanding awareness of this important study of ibudilast in ALS." Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased to initiate patient enrollment in this study. We look forward to providing further updates as the study progresses."

About the ALS Trial

This is a single center, randomized, double-blind, placebo-controlled, 6-month study designed to evaluate the safety, tolerability and clinical endpoint responsiveness of MN-166 (60 mg/day) when administered as an adjunct to riluzole (100 mg/day) in subjects with amyotrophic lateral sclerosis (ALS). This study consists of two treatment arms, MN-166 and matching placebo, and randomization will occur in a 2:1 ratio (MN-166: placebo). To be eligible, subjects must have a diagnosis of sporadic or familial ALS with onset of less than 3 years from first clinical weakness prior to screening and must be on a stable dose of riluzole for at least 1 month prior to study drug treatment. A total of approximately 60 male and female subjects from 18 to 80 years old, inclusive will be enrolled (40 subjects in the MN-166 group; 20 subjects in the placebo group).

Upon completion of the Double-blind Phase, subjects randomized to the placebo arm will continue for an additional 6 months and will receive open-label MN-166. If there are no safety or tolerability concerns in the MN-166 treated group, a decision will be made to extend participation to the MN-166 treated group into the Open-Label Extension (OLE) Phase. Otherwise, only the placebo-treated patients will participate in the OLE Phase.

The primary objective is to evaluate the safety and tolerability of MN-166 60 mg/day versus placebo when administered for 6 months with riluzole in subjects with ALS. The secondary objective is to evaluate the clinical endpoint responsiveness of MN-166 60 mg/day versus placebo when administered with riluzole in subjects with amyotrophic lateral sclerosis as measured by the following assessments:

- Functional activity as assessed by the Amyotrophic Lateral Sclerosis Functional Rating Scale-revised (ALSFRS-R)
- Respiratory function as measured by slow vital capacity (SVC), Maximum Inspiratory Pressure (MIP) also known as Negative Inspiratory Force (NIF) and Forced Expiratory Volume in 1 second (FEV_1) measured under SVC protocol
- Muscle strength measured by manual muscle testing (MMT) and instrumented hand grip dynamometry
- Non-invasive ventilation (NIV) utilization measured by clinically indicated prescription for NIV intervention and time to clinically indicated prescription for NIV intervention in each group

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 amyotrophic lateral sclerosis [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 nonalcoholic steatohepatitis (NASH) and idiopathic pulmonary fibrosis (IPF) and other fibrotic disease. 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, 2013 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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