



FDA Approves a New Clinical Protocol to Evaluate the Effects of MN-166 (ibudilast) on a Biomarker of ALS; MediciNova Plans to Initiate a Clinical Trial with MGH (Massachusetts General Hospital)

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LA JOLLA, Calif., Nov. 09, 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 the FDA (U.S. Food and Drug Administration) has approved the protocol of a new clinical trial in ALS patients, "A Single-Center, Open-Label Biomarker Study to Evaluate MN-166 (ibudilast) in Subjects with Amyotrophic Lateral Sclerosis (ALS)." This study is a collaborative effort between MediciNova, Inc. and Drs. Nazem Atassi and Haruhiko Banno, Principal Investigators at Massachusetts General Hospital's (MGH) Neurological Clinical Research Institute (NCRI) and Harvard Medical School to measure the effects of MN-166 on reducing brain microglial activation utilizing a biomarker in 15 subjects with ALS. This trial is expected to commence shortly.

"We are very pleased that this important regulatory step is now completed as we can continue clinical evaluation of MN-166 in the treatment of ALS. The objective of this trial is to evaluate MN-166 by measuring its effects using a novel imaging technology that will complement the conventional assays typically utilized in ALS trials," commented Yuichi Iwaki, MD, PhD, President and CEO of MediciNova, Inc.

About the ALS Biomarker Trial

This is an Open-Label, Proof-of-Mechanism, Phase 2a trial of ibudilast in ALS patients. Approximately 15 ALS subjects will be recruited and will be treated with ibudilast 50 mg twice daily for 36 weeks. The primary objective of this trial is to measure the effects of ibudilast on reducing brain microglial activation measured by [¹¹C]-PBR28-PET (biomarker) in subjects with ALS. Secondary objectives include evaluation of the safety, tolerability, and clinical outcomes (ALS functional rating scale [ALSFRS-R], slow vital capacity [SVC], and muscle strength [measured by HHD – hand-held dynamometry]) over 36 weeks.

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 potential 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, 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.

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