MediciNova Provides Update on Phase 2b Trial of MN-166 (ibudilast) in Progressive MS

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LA JOLLA, Calif., Sept. 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, as of September 15, 2014, the ongoing Phase 2b trial of MN-166 (ibudilast) in progressive multiple sclerosis (MS) had enrolled 150 of the 250 subjects planned to be enrolled. Enrollment is expected to be completed during the first quarter of 2015.

The study is being funded by the U.S. National Institutes of Health (NIH) and is being conducted by the NeuroNEXT clinical trial network within the National Institute of Neurological Disorders and Stroke (NINDS) at the NIH. The collaboration to perform the study includes 28 academic medical centers, MediciNova and advocacy support from the National Multiple Sclerosis Society. The principal investigator is Robert Fox, M.D., M.S., FAAN, Vice-Chair for Research, Neurological Institute, Cleveland Clinic.

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased to have completed 60% of the enrollment in this study. We look forward to providing further updates as the study progresses."

About the Progressive MS Trial

The Phase 2 Secondary and Primary Progressive Ibudilast NeuroNEXT trial in Multiple Sclerosis (SPRINT-MS) involves 28 enrolling clinical sites across the U.S. and is designed to evaluate the safety, tolerability and efficacy of MN-166 (ibudilast) administered twice daily to subjects with primary or secondary progressive multiple sclerosis (PPMS or SPMS, respectively). 250 qualifying subjects will be randomly assigned 1:1 to inactive control (placebo) or MN-166 (ibudilast) administered at a dose of 100 mg/day (i.e., 50 mg twice daily). The progressive MS subjects may be either untreated with long-term disease modifying therapy (DMT) or may continue either glatiramer acetate (GA) or interferon beta (IFNβ-1a or IFNβ-1b) treatment. Hence, randomization will be controlled (stratified) by two factors: therapy status (IFN/GA vs. no DMT) and disease status (PPMS vs. SPMS). The primary objectives of the study are 1) to evaluate the activity of ibudilast (MN-166) versus placebo at 96 weeks as measured by quantitative magnetic resonance imaging (MRI) analysis for whole brain atrophy using brain parenchymal fraction (BPF), and 2) to evaluate the safety and tolerability of ibudilast (MN-166) (100 mg/day) versus placebo administered orally in subjects with primary or secondary progressive multiple sclerosis. Secondary measures include disability, imaging analyses of brain and retinal tissue integrity, cortical atrophy, cognitive impairment, quality-of-life, and neuropathic pain. Exploratory objectives include pharmacokinetic and biomarker analyses.

About the Cooperative Effort

The collaborating entities include NeuroNEXT, the Cleveland Clinic, the National MS Society and MediciNova. NINDS's Network for Excellence in Neuroscience Clinical Trials, or NeuroNEXT, was created to conduct studies of treatments for neurological diseases through partnerships with academia, private foundations, and industry. NeuroNEXT sites include many of the leading medical centers in the U.S. The goals of NeuroNEXT include testing of promising neurological therapies in Phase 2 clinical trials, optimizing drug development time and cost components through an established clinical trials infrastructure, and the coordination of public/private sector efforts by leveraging NINDS' existing relationships with academic investigators and patient advocacy groups. A clinical coordinating center for the network is based at Massachusetts General Hospital and the data coordinating center is at University of Iowa. Dr. Fox and colleagues at the Cleveland Clinic collaborate with co-investigators at academic medical centers in the NeuroNEXT network. The National MS Society is providing patient advocate input and trial enrollment awareness. MediciNova holds the trial IND with the FDA Division of Neurology Products and additionally provides scientific and analytical support and drug and placebo supply.

About Progressive Multiple Sclerosis

According to the National MS Society, MS affects approximately 2.1 million people worldwide. Approximately 85% of MS patients are initially diagnosed with relapsing remitting MS (RRMS). Approximately 50% of RRMS patients transition into secondary progressive MS (SPMS) in which there are fewer or no relapses but gradual worsening of health. Approximately 10% of MS patients are diagnosed with primary progressive MS (PPMS) at onset and exhibit increasing disabilities in walking, vision, mental acuity, and other bodily functions that are typical in both PPMS and SPMS without ever experiencing relapses or remissions. Current therapies for multiple sclerosis (MS) affect the inflammatory response, but provide limited benefit for neurodegeneration and/or brain tissue repair. There is an unmet need for agents which may provide neuroprotection. A National MS Society multi-disciplinary focus group has described some of the key features of each type of MS as follows:

Primary-Progressive MS	Secondary-Progressive MS
Younger at onset of progression	Older at onset of progression
More likely in men	More likely in women
Generally takes longer to diagnose than relapsing MS	Diagnosed well after transition from relapsing MS to SPMS has already occurred

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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