MediciNova Announces MN-166 (ibudilast) Demonstrated a 26% Reduction in Confirmed Disability Progression in the SPRINT-MS Phase 2b Trial in Progressive MS: Potential Best-in-Disease Drug

February 1, 2018

LA JOLLA, Calif., Feb. 01, 2018 (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 the presentation of additional positive clinical data from the SPRINT-MS Phase 2b Trial of MN-166 (ibudilast) in progressive multiple sclerosis (progressive MS), which was conducted through the National Institutes of Health (NIH)-sponsored NeuroNEXT network. MN-166 (ibudilast) demonstrated a 26% reduction in the risk of confirmed disability progression compared to placebo (hazard ratio = 0.74), as measured by EDSS. Confirmed disability progression was a secondary endpoint in this Phase 2b trial but would be considered a primary endpoint in Phase 3. Based on the strong trends in reducing confirmed disability progression in this Phase 2b trial, MediciNova's power analysis has determined that a Phase 3 trial of MN-166 (ibudilast) that enrolls approximately 700 subjects will be sufficiently powered to achieve statistical significance for confirmed disability progression.

The data will be presented by Dr. Robert Naismith, Associate Professor of Neurology at Washington University School of Medicine and an investigator of the SPRINT-MS trial, on February 1, 2018 at 6:00 p.m. – 8:00 p.m. Pacific Time at the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum 2018 in San Diego, California.

As previously reported in October 2017, the SPRINT-MS Phase 2b Trial of MN-166 (ibudilast) in progressive MS achieved both primary endpoints.

Primary Endpoint #1: MN-166 (ibudilast) demonstrated a statistically significant 48% reduction in the rate of progression of whole brain atrophy compared to placebo (p=0.04) as measured by MRI analysis using brain parenchymal fraction (BPF).

Primary Endpoint #2: MN-166 (ibudilast) demonstrated a favorable safety and tolerability profile. There was not an increased rate of serious adverse events in the MN-166 (ibudilast) group compared to the placebo group. There were no opportunistic infections, no cancers, no cardiovascular events (i.e. no heart attacks or strokes), and no deaths related to MN-166 (ibudilast) treatment, as determined by an Independent Medical Monitor. There was no statistically significant difference in tolerability between the MN-166 (ibudilast) group and the placebo group. The most common treatment-emergent adverse events during the study were gastrointestinal adverse events, which occurred with a higher frequency in the MN-166 (ibudilast) group, and upper respiratory tract infections, which occurred with a higher frequency in the placebo group.

The study was conducted by the NeuroNEXT network with funding from the NIH National Institute of Neurological Diseases and Stroke (NINDS), the National Multiple Sclerosis Society, and MediciNova, Inc.

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc. commented, "We are extremely pleased with these results. Ibudilast's magnitude of reduction in disability progression was better than the data reported for the only drug approved for progressive MS and also better than the data reported for the other drugs being developed for progressive MS. With a convenient oral administration, a very favorable safety and tolerability profile compared to other MS drugs, and potentially better efficacy than any other drug for progressive MS, we believe ibudilast is well positioned to become the best-in-disease drug. As a next step, we plan to get formal feedback from FDA so we can move this program forward as fast as possible."

About the Progressive MS Trial

The Phase 2b Secondary and Primary Progressive Ibudilast NeuroNEXT trial in Multiple Sclerosis (SPRINT-MS) included 28 enrolling clinical sites across the U.S. and was designed to evaluate the safety, tolerability and activity of MN-166 (ibudilast) administered orally twice daily to subjects with primary progressive or secondary progressive multiple sclerosis (PPMS or SPMS, respectively). 255 qualifying subjects were randomly assigned 1:1 to inactive control (placebo) or MN-166 (ibudilast) administered at a dose of up to 100 mg/day (50 mg twice daily). The progressive MS subjects were either untreated with long-term disease modifying therapy (DMT) or continued on either glatiramer acetate (GA) or interferon beta (IFNβ-1a or IFNβ-1b) treatment. Hence, randomization was 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 to 1) 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) evaluate the safety and tolerability of ibudilast (MN-166) versus placebo in subjects with PPMS or SPMS. Additional 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. (www.neuronext.org). 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's existing relationships with academic investigators and patient advocacy groups. A clinical coordinating center for NeuroNEXT is led by Dr. Merit Cudkowicz and is based at Massachusetts General Hospital and the data coordinating center is led by Dr. Chris Coffey at the University of Iowa. Principal Investigator Dr. Robert Fox and colleagues at the Cleveland Clinic collaborate with co-investigators at academic medical centers in the NeuroNEXT network. The National MS Society provided patient advocate input, trial enrollment awareness, and additional funding. MediciNova holds the trial IND with the FDA's Division of Neurology Products and provides scientific and analytical support, as well as drug and placebo supply.

About Progressive Multiple Sclerosis

According to the National MS Society, MS affects approximately 2.3 million people worldwide. Approximately 85% of MS patients are initially diagnosed with relapsing remitting MS (RRMS). Most RRMS patients will eventually transition into SPMS in which there are fewer or no relapses but gradual worsening of neurologic function. Approximately 15% of MS patients are diagnosed with PPMS at onset and exhibit gradually increasing disability in walking, vision, mental acuity, and other bodily functions without experiencing relapses or remissions. Current therapies for MS affect the inflammatory response, but provide limited benefit for the neurodegeneration seen in progressive MS. There is a significant unmet medical need for agents that may provide neuroprotection in progressive MS.

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 is developing MN-166 for progressive MS and other neurological conditions such as ALS and substance abuse/addiction. 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. MediciNova has a portfolio of patents which cover the use of MN-166 (ibudilast) to treat various diseases including progressive MS, ALS, and drug addiction.

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 primary 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-001, MN-221 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-001, MN-221 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, 2016 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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