MediciNova Announces Results of Subgroup Analysis from the SPRINT-MS Phase 2b Trial of MN-166 (ibudilast) in Progressive MS

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LA JOLLA, Calif., April 01, 2019 (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 results from its subgroup analysis of the SPRINT-MS Phase 2b trial of MN-166 (ibudilast) in progressive multiple sclerosis (progressive MS).

This subgroup analysis was conducted based on recent feedback MediciNova received from the FDA that relapsing secondary progressive MS (i.e. secondary progressive MS with relapse) is different from non-relapsing secondary progressive MS (i.e. secondary progressive MS without relapse) as non-relapsing secondary progressive MS is the only type of secondary progressive MS without available therapy. The purpose of the subgroup analysis was to provide information about which types of progressive MS subjects responded best to MN-166 (ibudilast) treatment in terms of the clinically significant endpoint of the risk of confirmed disability progression compared to placebo, 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. Unlike the magnetic resonance imaging (MRI) endpoint of whole brain atrophy, which is not a clinical endpoint, confirmed disability progression is the most important clinical endpoint and is the basis for FDA approval of progressive MS drugs. As shown in the following table, the trends for reduction in the risk of confirmed disability progression were highest for the subgroup of subjects with Secondary Progressive MS without Relapse, in which MN-166 (ibudilast) demonstrated a 46% risk reduction compared to placebo as indicated by the hazard ratio of 0.538.

Risk of Confirmed Disability Progression:
Cox Hazard Ratios of the Two Treatments by Subgroup
Intent-To-Treat (ITT) Analysis Set

	Number of Subjects			
Subgroup	MN-166	Placebo	Hazard Ratio*	Risk Reduction
Primary Progressive MS	68	66	0.707	29%
Secondary Progressive MS with Relapse	9	6	1.153	-15%
Secondary Progressive MS without Relapse	52	54	0.538	46%

*MN-166 vs. Placebo

There is a large market opportunity for treating Secondary Progressive MS without Relapse as the vast majority of secondary progressive MS patients do not have relapses. For example, only 12% of secondary progressive MS patients had a relapse in the SPRINT-MS Phase 2b trial of MN-166 (ibudilast) in progressive MS which included 96 weeks of treatment. In addition to the large market opportunity, there is still no drug approved for long-term treatment of secondary progressive MS patients without relapses.

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc. commented, “We are excited with the results of our subgroup analysis. Although two drugs have recently received FDA approval for relapsing secondary progressive MS, there remains a very large unmet medical need for secondary progressive MS patients without relapses as there is still no drug approved for long-term treatment of these patients. Based on our extensive analysis of the SPRINT-MS data including this subgroup analysis, we are finalizing the optimal trial design for what we believe will be a very successful Phase 3 program and we plan to submit this trial design to the FDA shortly. With a convenient oral administration, a very favorable safety and tolerability profile, and the potential for better efficacy than other drugs for progressive MS, we believe ibudilast could become the best-in-disease drug.”

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 were 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 included disability, imaging analyses of brain and retinal tissue integrity, cortical atrophy, cognitive impairment, quality-of-life and neuropathic pain. Exploratory objectives included pharmacokinetic and biomarker analyses.

About the Cooperative Effort

The collaborating entities included 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 collaborated 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 provided 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) is a first-in-class, orally bioavailable, small molecule macrophage migration inhibitory factor (MIF) inhibitor and phosphodiesterase (PDE) -4 and -10 inhibitor that suppresses pro-inflammatory cytokines and promotes neurotrophic factors. It attenuates activated glial cells, which play a major role in certain neurological conditions. MN-166 (ibudilast)'s anti-neuroinflammatory and neuroprotective actions have been demonstrated in preclinical and clinical studies, which provide the rationale for treatment of progressive multiple sclerosis (MS) and other neurological diseases such as amyotrophic lateral sclerosis (ALS), glioblastoma (GBM), and substance abuse/addiction. MediciNova is developing MN-166 for progressive MS and other neurological conditions such as ALS, glioblastoma, substance abuse/addiction, and chemotherapy-induced neuropathy. MediciNova has a portfolio of patents which covers 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 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 multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), substance dependence (e.g., alcohol use disorder, methamphetamine dependence, opioid dependence) and glioblastoma (GBM), 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) and MN-029 (denibulin). 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, 2018 and its subsequent periodic reports on Form 10-Q and current reports on Form 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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