MediciNova Announces Phase 3 Clinical Trial Plan for MN-166 (ibudilast) in Progressive MS

July 11, 2019

LA JOLLA, Calif., July 11, 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 its plans for a Phase 3 clinical trial of MN-166 (ibudilast) in progressive multiple sclerosis (progressive MS) following feedback from the FDA (U.S. Food and Drug Administration).

Key elements of MediciNova's Phase 3 clinical trial plan for MN-166 (ibudilast) in progressive MS include the following:

• MediciNova's Phase 3 trial will enroll only subjects with secondary progressive MS without relapses. The rationale for enrolling this type of progressive MS is the following:

- The FDA agreed that a population of subjects with secondary progressive MS without relapses is an appropriate target population.
- MediciNova believes that subjects with secondary progressive MS without relapses will have the best clinical response to MN-166 (ibudilast) treatment, as compared to other types of progressive MS. As MediciNova previously reported in April 2019, results of the subgroup analysis of the SPRINT-MS Phase 2b trial of MN-166 (ibudilast) in progressive MS showed that the trends for reduction in the risk of confirmed disability progression, as measured by EDSS, were highest for the subgroup of subjects with secondary progressive MS without relapses, in which MN-166 (ibudilast) demonstrated a 46% risk reduction compared to placebo as indicated by the hazard ratio of 0.538.
- MediciNova believes that the unmet medical need is highest in subjects with secondary progressive MS without relapses as compared to other types of progressive MS. Unlike primary progressive MS and relapsing (or "active") secondary progressive MS, there are no drugs approved for long-term treatment of secondary progressive MS without relapses. In addition, secondary progressive MS without relapses is the largest subgroup of progressive MS patients. Based on the data from recently completed clinical trials in progressive MS, MediciNova believes that more than 80% of patients with secondary progressive MS do not have relapses.

• The FDA agreed that the primary endpoint of the Phase 3 trial should be time to 3-month confirmed disability progression, as measured by EDSS (Expanded Disability Status Scale). This is the same primary endpoint that was used in the Phase 3 trials of other drugs recently approved for progressive MS.

• MediciNova plans to conduct a single Phase 3 trial. The FDA acknowledged that a single trial can be the basis for marketing approval and the acceptability of a single trial to support drug approval depends on the study results. The two drugs approved for relapsing (or "active") secondary progressive MS in March 2019 were approved by the FDA after conducting a single Phase 3 trial.

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We are excited to announce our Phase 3 plan for MN-166 for progressive MS. 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 the vast majority of secondary progressive MS patients do not have relapses and there is still no drug approved for long-term treatment of these patients. 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 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 secondary progressive MS (SPMS) in which there are fewer or no relapses but gradual worsening of neurologic function. Approximately 15% of MS patients are diagnosed with primary progressive MS (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), amyotrophic lateral sclerosis (ALS), and other neurological diseases such as glioblastoma (GBM), and substance abuse/addiction. MediciNova is developing MN-166 for progressive MS, ALS, and other neurological conditions such as degenerative cervical myelopathy (DCM), glioblastoma, substance abuse/addiction, and chemotherapy-induced peripheral 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 MS, ALS, degenerative cervical myelopathy (DCM), 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 (i) our ability to successfully complete a Phase 3 clinical trial of MN-166 in patients with secondary progressive MS without relapses, (ii) our expectations regarding the FDA regulatory pathway for MN-166, including our ability to obtain regulatory approval for MN-166 with a single Phase 3 clinical trial, (iii) subjects with secondary progressive MS without relapses will continue to respond to MN-166 consistent with our Phase 2 clinical trial results and (iv) our ability to successfully compete against other approved MS drugs, assuming we obtain regulatory approval for MN-166. 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, we may not successfully complete our Phase 3 clinical trial of MN-166 on a timely basis or at all, 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, 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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