MediciNova Announces Initiation of NIHR Grant-Funded Phase 2/3 Trial of MN-166 (ibudilast) for the Treatment of Degenerative Cervical Myelopathy in Collaboration with the University of Cambridge

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LA JOLLA, Calif., Aug. 06, 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 that it plans to initiate a Phase 2/3 trial of MN-166 (ibudilast) in degenerative cervical myelopathy (DCM) in collaboration with the University of Cambridge.

This clinical trial is being conducted under an agreement between MediciNova, the University of Cambridge, and Cambridge University Hospitals NHS Foundation Trust. Funding for this clinical trial is being provided by the National Institute for Health Research (NIHR) in the United Kingdom (UK). The Principal Investigator is Dr. Mark Kotter, NIHR Clinician Scientist, Honorary Consultant in Neurosurgery at the University of Cambridge. This trial will evaluate MN-166 (ibudilast) as an adjuvant treatment for DCM following spinal surgery and determine whether MN-166 (ibudilast) is more effective than placebo in improving outcomes after spinal surgery. Nonclinical studies have shown that inhibiting PDE-4, a well-established mechanism of action of MN-166 (ibudilast), promotes nerve growth in a traumatic spinal cord injury model. This re-growth in the spinal cord may lead to partial or complete recovery of function in DCM patients. MediciNova will provide the study drug supply, regulatory support, and safety monitoring support.

Mark Kotter, MD, Principal Investigator of the study, commented, “We are excited to collaborate with MediciNova to evaluate MN-166 for the treatment of degenerative cervical myelopathy. We believe MN-166’s ability to induce nerve re-growth has potential clinical utility in DCM.”

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, “We are very pleased to collaborate with Dr. Kotter to explore the effects of MN-166 as a pharmacotherapy in DCM. We appreciate the funding and support by NIHR.”

About the Degenerative Cervical Myelopathy Trial

The clinical trial, titled *“**Re**generation in **Ce**rvical **De**generative **Myelopathy** – a multi-centre, double-blind, randomised, placebo-controlled trial assessing the efficacy of ibudilast as an adjuvant treatment to decompressive surgery for degenerative cervical myelopathy*,” plans to enroll 25 - 80 subjects in the initial phase of the trial (stage 1) with 300 - 350 subjects overall. Two to three months prior to decompressive surgery, eligible subjects will be randomized to receive either MN-166 (ibudilast) or matching placebo at doses up to 100 mg/day. Study drug treatment will continue for 8 months and subjects will be evaluated at the clinic at 3, 6, and 12 months following surgery. The primary endpoint is the modified Japanese Orthopaedic Association (mJOA) Score, which evaluates motor dysfunction in upper and lower extremities, loss of sensation, and sphincter dysfunction, at 6 months after surgery. Other study outcome measures include neurological exam, GRASSP (measures hand function), Spinal Cord Independence Measure version 3, or SCIMv3 (measures activities of daily independent living), 30-meter walk test, Neck Disability Index (NDI), pain rating using the Visual Analog Scale (VAS), EQ-5D and SF-36 questionnaires (measures quality of life), QuickDASH (measures disabilities of the arm, shoulder, and hand), and safety and tolerability.

About Degenerative Cervical Myelopathy

According to Myelopathy.org, degenerative cervical myelopathy (DCM) is defined as compression of the spinal cord in the neck which can lead to paralysis. DCM is a common, progressive neurological disease caused by aging, arthritis, and degenerative spinal conditions such as spinal stenosis and central disc herniation. According to the American Association of Neurological Surgeons, more than 200,000 cervical procedures are performed each year to relieve compression on the spinal cord or nerve roots. Compression of spinal nerves leads to neurological dysfunction such as numbness, tingling, pain and stiffness in the neck and pain and numbness in the arms, fingers, or hands. Patients may experience muscular abnormalities including, but not limited to, problems with balance and walking, incoordination, muscle weakness in arms, shoulders, or hands, rhythmic muscle spasm, stiff muscles, loss of muscle, overactive reflexes, and loss of bladder and bowel control. Depending on the severity of symptoms, the options for treatment of DCM are a movement-restricting collar, physical therapy, pain relievers, muscle relaxants, and surgery. Currently, no cure exists and there is no approved medication to treat DCM.

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 multiple sclerosis (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., alcohol use disorder, 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, 2017 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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