



MediciNova Participated in the RECEDE Phase 3 Degenerative Cervical Myelopathy Trial Kick-off Meeting, DCM Symposium and the Official Launch of Myelopathy.org in London, United Kingdom

May 7, 2019

Dr. Yuichi Iwaki, M.D., Ph.D., President and Chief Executive Officer, invited speaker at the official launch of Myelopathy.org at The British Parliament House of Lords, shared his thoughts on supporting innovative science

LA JOLLA, Calif., May 07, 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 participation at the Kick-off Meeting for the Phase 3 trial, "**REgeneration in CErvical DEgenerative Myelopathy (RECEDE Myelopathy)**", a collaboration with University of Cambridge researchers, as well as at the first UK Academic Spine Symposium, which took place on Tuesday, May 7, 2019 at the Royal Society of Medicine in London, UK.

Following the events, Yuichi Iwaki, M.D., Ph.D., President and Chief Executive Officer gave a speech for the official launch of *Myelopathy.org* hosted by Lord Carter of Coles in the UK Parliament House of Lords on supporting innovative science through its collaboration in the RECEDE Myelopathy Phase 3 trial to evaluate MN-166 (ibudilast) in degenerative cervical myelopathy (DCM) patients. Fellow speakers included H.E. Mr. Koji Tsuruoka, Ambassador Extraordinary and Plenipotentiary, Embassy of Japan in the UK as well as world-renown Spine Surgeon and Researcher, Professor Michael Fehlings, M.D., Ph.D., Vice-Chair Research for the Department of Surgery at the University of Toronto.

The RECEDE Myelopathy Phase 3 trial is being conducted under an agreement between MediciNova, the University of Cambridge, and Cambridge University Hospitals NHS Foundation Trust. Funding for the trial is being provided by the United Kingdom National Institute for Health Research (NIHR). Its Chief Investigator is Mark Kotter, M.D., Ph.D., NIHR Clinician Scientist and Consultant in Neurosurgery at the University of Cambridge. The 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.

Myelopathy.org, founded by myelopathy sufferer Iwan Sadler, Dr. Kotter and his colleagues, is the world's first patient support charity for DCM, a collaborative initiative between researchers, health professionals, myelopathy patients and their advocates.

Mark Kotter, MD PhD, Chief Investigator of the RECEDE Myelopathy study, commented, "We are very excited to collaborate with MediciNova to evaluate MN-166 for the treatment of DCM. MN-166 has the potential to benefit DCM by addressing the three hallmarks of DCM pathology: by promoting nerve re-growth, stimulating the repair of myelin sheaths, and by alleviating the consequences of reduced blood flow in the spinal cord. We believe that MN-166 has potential clinical utility in DCM. We are also highly appreciative to MediciNova and the Japanese Embassy's support for Myelopathy.org, the first charity for the DCM community."

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased to provide our promising new treatment, MN-166 to DCM patients and we are excited to work in collaboration with Dr. Kotter to explore the effects of MN-166 as a pharmacotherapy in DCM. We are also highly appreciative of the funding and support by NIHR."

About the RECEDE Myelopathy Trial

The clinical trial, titled "**REgeneration in CErvical DEgenerative 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 up to 80 subjects in the initial phase of the trial (stage 1) with planned enrollment of 362 subjects, overall. Two to three months prior to decompressive surgery, eligible subjects will be randomly assigned to receive either MN-166 (ibudilast) at doses up to 100 mg/day or matching placebo. 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 study was designed on the basis of patient input, including a survey of 481 patients hosted by Myelopathy.org regarding their recovery priorities. Its two co-primary endpoints assess changes in pain and function 6 months after surgery as compared to baseline at enrollment. Pain will be measured using the Visual Analogue Scale (VAS). Changes in function will be measured using the modified Japanese Orthopaedic Association (mJOA) Score, which evaluates motor dysfunction in upper and lower extremities, loss of sensation, and sphincter dysfunction. 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), 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 British Medical Journal Article (*BMJ* 2018; 360 doi: <https://doi.org/10.1136/bmj.k186>) 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, central disc herniation, and ossification of the posterior longitudinal ligament (oPLL). Information of the American Association of Neurological Surgeons, states that 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 Myelopathy.org

Myelopathy.org is the first nonprofit organization dedicated to DCM. Its mission is “to raise awareness and support patients, carers and professionals who live and deal with the condition”.

Dr Mark Kotter, Ben Davies, trainee neurosurgeon and Research Fellow of the Royal College of Surgeons, and myelopathy-sufferer Mr. Iwan Sadler, co-founded Myelopathy.org as a forum for individuals with myelopathy where they can come together and share their experiences. It aims to provide people with myelopathy a unified voice, to educate health professionals and to disseminate accurate information about DCM. Further aims are to support research and to effect change, for example by improving diagnosis of DCM and patient pathways.

About MN-166 (ibudilast)

MN-166 (ibudilast) is a first-in-class, orally bioavailable, small molecule phosphodiesterase (PDE) -4 and -10 inhibitor and macrophage migration inhibitory factor (MIF) inhibitor that suppresses pro-inflammatory cytokines and promotes neurotrophic factors. It modulates 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 amyotrophic lateral sclerosis (ALS), progressive multiple sclerosis (MS) and other neurological diseases such as glioblastoma (GBM), and substance abuse/addiction. MediciNova is developing MN-166 for ALS, progressive MS and other neurological conditions such as degenerative cervical myelopathy (DCM), 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 ALS, progressive MS, 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 multiple sclerosis (MS), amyotrophic lateral sclerosis (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 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.*

INVESTOR CONTACT:

Geoff O'Brien
Vice President
MediciNova, Inc.
info@medicinova.com



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