MediciNova Announces MN-166 (ibudilast) Identified as Potential Beneficial Pharmacotherapy for Treatment of Degenerative Cervical Myelopathy in Global Spine Journal

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LA JOLLA, Calif., Feb. 28, 2022 (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 MN-166 (ibudilast) was discussed as a potential beneficial pharmacological agent for the treatment of degenerative cervical myelopathy (DCM) in *Global Spine Journal*.

The publication entitled “Developing Novel Therapies for Degenerative Cervical Myelopathy [AO Spine RECODE-DCM Research Priority Number 7]: Opportunities from Restorative Neurobiology” and co-authored by MediciNova’s collaborator, Dr. Mark Kotter, Professor, Neurosurgery Unit, Department of Clinical Neuroscience, University of Cambridge, UK, and colleagues, discussed contemporary therapies that may hold therapeutic value in three broad categories of neuroprotection, neuroregeneration, and neuromodulation. Among those reviewed, the authors discuss the attributes of MN-166 (ibudilast) that support its use in DCM. The combination of anti-inflammatory, neuroprotective, and neuroregenerative properties of MN-166 (ibudilast) is the basis for RECEDE-Myelopathy, a Phase 3, double-blind, randomized controlled trial assessing its efficacy as an adjuvant treatment to decompressive surgery for DCM on mJOA (modified Japanese Orthopaedic Association) score and neck pain.

Key take-aways in the publication include:

- Chronic spinal cord compression due to DCM leads to ischaemia, neuroinflammation, demyelination, and neuronal loss.
- People with DCM often develop and then suffer from lifelong disability, with less than 5% making a full recovery despite surgical decompression.
- An increase in activated microglia and macrophages has been observed at the site of chronic spinal cord compression and is a source of pro-inflammatory cytokines and can lead to further cell death by necrosis and apoptosis.
- MN-166 (ibudilast) has been shown to exhibit central anti-inflammatory, neuroprotective, and neurotrophic/neuroregenerative effects by inhibition of phosphodiesterase (PDE4 and PDE10) and macrophage migration inhibitory factor (MIF).
- This combination of effects, which leads to attenuation of glial cell activation and enhancement of neurotrophic/neuroregenerative factors, makes a compelling case to assess MN-166 (ibudilast) for the treatment of DCM.
- MN-166 (ibudilast) is the only drug currently being evaluated in Phase 3 as a regenerative medicine for the treatment of DCM.

Kazuko Matsuda, MD, PhD, MPH, Chief Medical Officer of MediciNova, Inc. commented, “We are encouraged that MN-166 (ibudilast) was identified by this highly reputable team of research collaborators as a potential beneficial pharmacotherapy for the treatment of DCM, a disease from which very few patients make a full recovery.”

About AO Spine RECODE-DCM Research Priority 7

The AO Spine RECODE-DCM is an international initiative to create a "research toolkit" to accelerate knowledge, discovery, and improve outcomes in degenerative cervical myelopathy. It has 10 research priorities. The seventh of these is defined as "Novel Therapies". This article is published as one of a series of reviews related to AO Spine RECODE-DCM featured in *Global Spine Journal*.

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) is a small molecule compound that inhibits phosphodiesterase type-4 (PDE4) and inflammatory cytokines, including macrophage migration inhibitory factor (MIF). It is in late-stage clinical development for the treatment of neurodegenerative diseases such as ALS (amyotrophic lateral sclerosis), progressive MS (multiple sclerosis), and DCM (degenerative cervical myelopathy); and for glioblastoma, CIPN (chemotherapy-

induced peripheral neuropathy), and substance use disorder. In addition, MN-166 (ibudilast) is being evaluated in patients that are at risk for developing acute respiratory distress syndrome (ARDS).

About MediciNova

MediciNova, Inc. is a clinical-stage biopharmaceutical company developing a broad late-stage pipeline of novel small molecule therapies for inflammatory, fibrotic and neurodegenerative diseases. Based on two compounds, MN-166 (ibudilast) and MN-001 (tipelukast), with multiple mechanisms of action and strong safety profiles, MediciNova has 11 programs in clinical development. MediciNova's lead asset, MN-166 (ibudilast), is currently in Phase 3 for amyotrophic lateral sclerosis (ALS) and degenerative cervical myelopathy (DCM) and is Phase 3-ready for progressive multiple sclerosis (MS). MN-166 (ibudilast) is also being evaluated in Phase 2 trials in glioblastoma, patients at risk of developing acute respiratory distress syndrome (ARDS), and substance dependence. MN-001 (tipelukast) was evaluated in a Phase 2 trial in idiopathic pulmonary fibrosis (IPF) and is in preparation for a second Phase 2 trial in nonalcoholic steatohepatitis (NASH). MediciNova has a strong track record of securing investigator-sponsored clinical trials funded through government grants.

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, 2021 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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