# MediciNova Announces European Medicines Agency Recommends Orphan Medicinal Product Designation for MN-166 (ibudilast) for Amyotrophic Lateral Sclerosis

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LA JOLLA, Calif., Nov. 10, 2016 (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 the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products (COMP) has issued a positive opinion recommending orphan medicinal product (orphan-drug) designation for MN-166 (ibudilast) for the treatment of amyotrophic lateral sclerosis (ALS). Orphan-drug designation offers potential benefits including protocol assistance, fee waivers, and 10-year market exclusivity once the medicine is on the market in Europe.

This is the first orphan medicinal product designation that MediciNova has received from the EMA. The process required a thorough scientific evaluation including establishing "sufficient justification" under the EMA's COMP criteria and that MN-166 (ibudilast) "will be of significant benefit to those affected by the condition…"

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased to receive a positive opinion recommending orphan-drug designation for MN-166 for ALS in the European Union, a recommendation that complements our recently granted orphan-drug designation in the U.S. This is an important milestone for the development of a promising new therapeutic treatment for ALS, a life-threatening, rare disease for which riluzole is the only currently-approved treatment option in the EU and U.S. Currently, we have two ongoing clinical trials to evaluate MN-166 in ALS in collaboration with researchers at Carolinas HealthCare System's (CHS) Neuromuscular/ALS-MDA Center and Massachusetts General Hospital. MN-166 (ibudilast) demonstrated positive trends in the interim efficacy data from the mid-study analysis of the CHS Neuromuscular/ALS-MDA Center study. This interim data, along with previously reported positive ALS preclinical study data, was submitted to EMA COMP to address the scientific rationale for orphan medicinal product designation to establish the medical basis for the use of MN-166 (ibudilast) for ALS."

**About Amyotrophic Lateral Sclerosis**
Amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease, is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. The nerves lose the ability to trigger specific muscles, which causes the muscles to become weak. As a result, ALS affects voluntary movement and patients in the later stages of the disease may become totally paralyzed. Life expectancy of an ALS patient is usually 2-5 years. According to the ALS Association, there are approximately 20,000 ALS patients in the U.S. and approximately 6,000 people in the U.S. are diagnosed with ALS each year. Publications estimate that there are approximately 29,000 ALS patients in the EU. Riluzole is the only pharmaceutical treatment approved for ALS in the U.S. and EU, but it has limited efficacy.

**About Orphan Medicinal Product Designation**
Orphan medicinal product designation in the EU refers to pharmaceuticals that have been developed for the treatment of life-threatening or chronically debilitating rare diseases with reported prevalence of fewer than 5 patients per 10,000 population. Orphan medicinal product designation allows a more straightforward clinical development path for the drug and allows the sponsor to receive significant potential economic, scientific, and regulatory benefits, including reduced fees and taxes, access to free protocol assistance and scientific advice by the EMA, and a 10-year period of marketing exclusivity.

**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 ALS and other neurological conditions such as progressive MS and drug use disorders. 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., ALS and progressive MS), drug use disorders and chronic neuropathic pain. MediciNova has a portfolio of patents which cover the use of MN-166 (ibudilast) to treat various diseases including ALS, progressive MS, and drug use disorders.

**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 commercial focus on the U.S. and European markets. MediciNova's current strategy is to focus on MN-166 (ibudilast) for neurological disorders such as ALS, progressive MS and drug use disorders (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, 2015 and its subsequent periodic reports on Forms 10-Q and 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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