MediciNova Announces FDA Granted Orphan Drug Designation to MN-166 (ibudilast) for Krabbe Disease

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LA JOLLA, Calif., June 3, 2015 (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 U.S. Food and Drug Administration (FDA) has granted orphan-drug designation to MN-166 (ibudilast) for treatment of Krabbe disease. MediciNova previously opened an Investigational New Drug (IND) application with the Division of Neurology Products (DNP) for MN-166 (ibudilast).

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased to receive orphan-drug designation for MN-166 for Krabbe Disease, a rare disease for which hematopoietic stem cell transplantation, the only currently available treatment option, is not without potential risk to the patient and is limited in efficacy. As we already have an open IND, we plan to finalize a protocol and submit it to FDA in order to conduct a clinical trial of MN-166 in Krabbe Disease."

About Krabbe Disease

Krabbe disease is a rare genetic degenerative disorder for which there is no cure and is generally fatal before two years of age. Krabbe disease has 4 clinical subtypes (Types 1 - 4), distinguished by age of onset. In the vast majority of cases, the symptoms of Krabbe disease begin at age 0 - 6 months (Type 1 early infantile form). Initial signs and symptoms typically include irritability (e.g., excessive crying), limb spasticity, absent reflexes, muscle weakness, feeding difficulties, episodes of fever with no sign of infection, stiff posture, and slowed or regressed neurocognitive development. As the disease progresses, muscles continue to weaken, affecting the infant's ability to move, chew, swallow, and breathe. Affected infants also experience vision loss and seizures, regress rapidly to a decerebrate condition and usually succumb to the disease before their 2nd birthday. Approximately 10% present symptoms later in life, including in adulthood (Types 2 - 4). Progressive loss of vision, difficulty walking, decline in thinking skills, loss of manual dexterity, and muscle weakness are the most common initial symptoms in this form of the disorder, however, signs and symptoms vary considerably among affected individuals. Patients with late-onset Krabbe Disease regress at a slower pace and have the potential to live significantly longer than patients diagnosed in early infancy.

About Orphan Drug Designation

Drugs that receive orphan-drug designation from FDA are entitled to seven years of marketing exclusivity if they are approved by the FDA for the same rare disease. The Orphan Drug Designation program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug.

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 licensed MN-166 (ibudilast) from Kyorin Pharmaceutical Co., Ltd. for potential utility in relapse-remitting multiple sclerosis (RRMS). Intellectual property was additionally established or obtained by MediciNova in progressive MS and other neurological conditions. 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 amyotrophic lateral sclerosis (ALS)), substance abuse/addiction and chronic neuropathic pain.

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. 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. 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, 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, 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, 2014 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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