FDA Grants Fast Track Designation for MediciNova's MN-166 (ibudilast) for Progressive Multiple Sclerosis

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LA JOLLA, Calif., March 22, 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 it has received Fast Track designation from the U.S. Food and Drug Administration (FDA) for the development of MN-166 (ibudilast) for the treatment of patients with progressive multiple sclerosis (progressive MS). Progressive MS includes both primary progressive MS (PPMS) and secondary progressive MS (SPMS). Fast Track is a process designed to facilitate the development and expedite the review of drugs that are intended to treat serious or life-threatening diseases and demonstrate the potential to address unmet medical needs for such diseases. An important feature of the FDA's Fast Track program is that it emphasizes frequent communication between the FDA and the sponsor throughout the entire drug development and review process to improve the efficiency of product development. Accordingly, Fast Track status can potentially lead to a shortened timeline to ultimate drug approval.

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased that MN-166 has received Fast Track Designation for progressive MS and believe this validates its potential to address unmet medical needs for this serious disease. We look forward to providing further updates from our ongoing clinical trial in progressive MS."

About Fast Track Designation

According to the FDA, in order to be granted Fast Track designation, a drug must (1) be intended for the treatment of a serious or life-threatening disease or condition; and (2) demonstrate the potential to address unmet medical needs for the disease or condition.

A drug that receives Fast Track designation may be eligible for:

- More frequent meetings with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval;
- Accelerated Approval, i.e., approval based on an effect on a surrogate, or substitute endpoint reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality;
- Priority Review, with an FDA goal for completing review within six months of submission; and
- Rolling Review, which means that a sponsor can submit completed sections of its New Drug Application (NDA) for review by the FDA, rather than waiting until every section of the application is completed before the entire application can be reviewed.

About Progressive Multiple Sclerosis

In multiple sclerosis (MS), an abnormal response of the body's immune system is directed against the central nervous system including the brain, spinal cord and optic nerves. The immune system attacks myelin, the fatty substance that surrounds and insulates the nerve fibers, as well as the nerve fibers themselves. Damage to the myelin sheath and nerve fibers causes distortion or interruption of nerve impulses traveling to and from the brain and spinal cord, resulting in a wide variety of symptoms. More common symptoms include fatigue, walking difficulties, numbness, spasticity, weakness, vision problems, dizziness, bladder problems, sexual problems, bowel problems, pain, cognitive changes, emotional changes, and depression. According to the National Multiple Sclerosis Society, multiple sclerosis (MS) affects approximately 2.3 million people worldwide. Approximately 85% of MS patients are initially diagnosed with relapsing remitting MS (RRMS) which is defined by inflammatory attacks on myelin with new or increasing neurologic symptoms. Most RRMS patients transition into secondary progressive MS (SPMS) in which there is progressive worsening of neurologic function (accumulation of disability) over time but few or no relapses. Approximately 10% of MS patients are diagnosed with primary progressive MS (PPMS) which is characterized by worsening neurologic function (accumulation of disability) from the onset of symptoms. Current therapies for MS affect the inflammatory response in RRMS, but provide limited or no benefit for neurodegeneration and/or brain tissue repair. There is a major unmet medical need for drugs which may provide neuroprotection for progressive MS patients.

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 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 including 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 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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