MediciNova Announces Clinical Data from Subgroup Analyses of Completed Clinical Trial of MN-166 (ibudilast) in ALS

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LA JOLLA, Calif., July 09, 2018 (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 clinical data from ad-hoc subgroup analyses of MediciNova's completed clinical trial of MN-166 (ibudilast) in ALS (amyotrophic lateral sclerosis), which was conducted at Carolinas HealthCare System's Neuromuscular/ALS-MDA Center at Carolinas HealthCare System Neurosciences Institute.

The ad-hoc subgroup analyses include data from (1) the "Early ALS subgroup" which is 31 subjects who had either bulbar onset or upper limb onset out of a total of 49 subjects without non-invasive ventilation in the full analysis set and (2) the "Early ALS + NIV subgroup" which is 39 subjects who had either bulbar onset or upper limb onset out of a total of 67 subjects with and without non-invasive ventilation in the full analysis set. The full analysis set includes all randomized subjects who received at least 14 days of study drug and had at least one post-dose efficacy measurement. The subgroup analyses were completed for the ALSFRS-R total score, the ALSAQ-5 score, and the Manual Muscle Test. A responder was defined as a subject who did not worsen on the score (i.e., the subject improved on the score or had no change on the score) at the end of the 6-month double-blind period. Results of the subgroup analyses are as follows:

Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R) Total Score

ALSFRS-R, which includes 12 questions that can have a score of 0 to 4, measures functional activity and has been useful in diagnosing and measuring disease progression.

Early ALS subgroup

- There was a higher percentage of responders in the MN-166 (ibudilast) group compared to the placebo group. 30.0% (6/20) of subjects in the MN-166 (ibudilast) group were responders on the ALSFRS-R total score compared to 9.1% (1/11) of subjects in the placebo group.
- There was a higher percentage of subjects who improved in the MN-166 (ibudilast) group compared to the placebo group. 25.0% (5/20) of subjects in the MN-166 (ibudilast) group improved on the ALSFRS-R total score compared to 0.0% (0/11) of subjects in the placebo group at the end of the 6-month double-blind period.

Early ALS + NIV subgroup

- There was a higher percentage of responders in the MN-166 (ibudilast) group compared to the placebo group. 26.9% (7/26) of subjects in the MN-166 (ibudilast) group were responders on the ALSFRS-R total score compared to 7.7% (1/13) of subjects in the placebo group.
- There was a higher percentage of subjects who improved in the MN-166 (ibudilast) group compared to the placebo group. 23.1% (6/26) of subjects in the MN-166 (ibudilast) group improved on the ALSFRS-R total score compared to 0.0% (0/13) of subjects in the placebo group at the end of the 6-month double-blind period.

ALSFRS-R Total Score		MN-166 + riluzole	Placebo + riluzole	p value
Early ALS subgroup	Responder	30.0% (6/20)	9.1% (1/11)	p=0.1916
	Improver	25.0% (5/20)	0.0% (0/11)	p=0.0912
Early ALS + NIV subgroup	Responder	26.9% (7/26)	7.7% (1/13)	p=0.1644
	Improver	23.1% (6/26)	0.0% (0/13)	p=0.0706

Amyotrophic Lateral Sclerosis Assessment Questionnaire (ALSAQ-5) Score

ALSAQ-5 measures the physical mobility, activities of daily living and independence, eating and drinking, communication, and emotional functioning.

Early ALS subgroup

- There was a higher percentage of responders in the MN-166 (ibudilast) group compared to the placebo group. 60.0% (12/20) of subjects in the MN-166 (ibudilast) group were responders on the ALSAQ-5 score compared to 9.1% (1/11) of subjects in the placebo group (p=0.0071).

Early ALS + NIV subgroup

- There was a higher percentage of responders in the MN-166 (ibudilast) group compared to the placebo group. 50.0% (13/26) of subjects in the MN-166 (ibudilast) group were responders on the ALSAQ-5 score compared to 23.1% (3/13) of subjects in the placebo group.

ALSAQ-5 Score Responder	MN-166 + riluzole	Placebo + riluzole	p value
Early ALS subgroup	60.0% (12/20)	9.1% (1/11)	p=0.0071
Early ALS + NIV subgroup	50.0% (13/26)	23.1% (3/13)	p=0.1017

Manual Muscle Testing (MMT)

MMT measures the muscle strength of an ALS subject.

Early ALS subgroup

- There was a higher percentage of responders in the MN-166 (ibudilast) group compared to the placebo group. 35.0% (7/20) of subjects in the MN-166 (ibudilast) group were responders on the MMT score compared to 18.2% (2/11) of subjects in the placebo group.

Early ALS + NIV subgroup

- There was a higher percentage of responders in the MN-166 (ibudilast) group compared to the placebo group. 34.6% (9/26) of subjects in the MN-166 (ibudilast) group were responders on the MMT score compared to 23.1% (3/13) of subjects in the placebo group.

MMT Score Responder	MN-166 + riluzole	Placebo + riluzole	p value
Early ALS subgroup	35.0% (7/20)	18.2% (2/11)	p=0.2866
Early ALS + NIV subgroup	34.6% (9/26)	23.1% (3/13)	p=0.3626

MediciNova has requested a meeting with the FDA to discuss the study design for the next ALS trial.

Yuichi Iwaki, MD, PhD, President and Chief Executive Officer of MediciNova, Inc., commented, "We are very pleased with the results of these new analyses which indicate that MN-166 could improve outcomes in this devastating and fatal disease. We believe this is a direct result of MN-166's mechanism of enhancing the production of neurotrophic factors including nerve growth factor. We look forward to meeting with the FDA."

About the ALS Trial

MediciNova, in collaboration with Dr. Benjamin Rix Brooks, Director, Carolinas Neuromuscular/ALS-MDA Center at Carolinas HealthCare System Neurosciences Institute, evaluated 60 mg of MN-166 (ibudilast) per day in early and advanced stage ALS patients. All subjects in the study received 100 mg of riluzole per day. This trial was a randomized, double-blind, placebo-controlled study which included a six-month treatment period followed by a six-month open-label extension. The primary endpoint was safety and tolerability and the study also evaluated several efficacy endpoints including functional activity (ALSFRS-R). Data analyzed from the 51 early ALS subjects (the intent-to-treat/ITT population) was presented at the 28th International Symposium on ALS/MND in Boston, MA in December 2017. There was a higher percentage of responders on the ALSFRS-R total score, MMT (manual muscle testing) and ALSAQ-5 score (subjective quality-of-life questionnaire) in the MN-166 (ibudilast) group compared to the placebo group. This was the first study of MN-166 (ibudilast) in ALS and the study provides the necessary clinical data for powering assumptions for the next study of MN-166 (ibudilast) in ALS.

About ALS

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 completely 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.

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 progressive multiple sclerosis (MS) and other neurological conditions such as ALS and substance abuse/addiction. 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 ALS), substance abuse/addiction and chronic neuropathic pain. MediciNova has a portfolio of patents which cover the use of MN-166 (ibudilast) to treat various diseases including progressive MS, ALS, 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 MS, ALS and substance dependence (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, 2017 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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