

Press release

NeuroVive Pharmaceutical AB (publ)
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NeuroVive initiates second part of its ongoing KL1333 Phase Ia/b clinical study

Lund, Sweden, 4 July 2019, NeuroVive Pharmaceutical AB (Nasdaq Stockholm: NVP, OTCQX: NEVPF) today announced that the company has initiated the second part in its ongoing Phase Ia/b clinical study with KL1333, NeuroVive's candidate drug for chronic treatment of genetic mitochondrial diseases, following successful completion of the first part.

NeuroVive has now initiated the repeated dosing of healthy volunteers in the second part of its Phase Ia/b clinical study of KL1333. The first cohort of the study, in which the effect of food intake on the uptake of KL1333 after a single dose was assessed in healthy volunteers, has been successfully completed and based on the review of that data it has been decided to continue the second part of the study, where multiple ascending doses in healthy volunteers will be evaluated.

The focus of the ongoing study, conducted in the UK, is to examine the safety profile and the metabolic changes of KL1333 in healthy volunteers and in patients. The study has an adaptive design, which means that the number of cohorts and the dose levels for the cohorts will be modified, on the basis of results from the previous cohort. This will maximize the information from the study. The third and final part of the study will evaluate repeated doses of KL1333 in mitochondrial disease patients, which will be the first time KL1333 is given to patients.

"We are truly excited about the data from the first cohort in our clinical study with KL1333. The drug properties and safety data observed are reassuring and promising as we now proceed into the second part of the study", said Magnus Hansson, Chief Medical Officer and Vice President Preclinical and Clinical Development at NeuroVive.

"The progress in the KL1333 program is a great step towards our plan of taking the project to a clinical efficacy study next year and important to our company. Our ultimate goal is to bring this possible life changing treatment to the market and to patients with mitochondrial disease, who currently have a high unmet medical need", said CEO Erik Kinnman.

This information is information that NeuroVive Pharmaceutical AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out below, at 2.30 p.m. CEST on 4 July 2019.

For more information please contact:

Catharina Johansson, CFO, IR & Communications
+46 (0)46-275 62 21, ir@neurovive.com

NeuroVive Pharmaceutical AB (publ)
Medicon Village, SE-223 81 Lund, Sweden
Tel: +46 (0)46 275 62 20 (switchboard)

NeuroVive Pharmaceutical AB (publ) - the mitochondrial medicine company. The company is listed on Nasdaq Stockholm, Small Cap, under the ticker symbol NVP. The share is also traded on the OTC Markets Group Inc market in the US. NeuroVive Pharmaceutical (OTC: NEVPF) trades on the OTCQX Best Market. Investors can find Real-Time quotes and market information for the company at www.otcmarkets.com/stock/NEVPF/quote

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About genetic mitochondrial diseases

Genetic mitochondrial diseases are metabolic diseases that affect the ability of cells to convert energy. The disorders can manifest differently depending on the organs affected by the genetic defects and are viewed as clinical syndromes. An estimated 12 in every 100,000 people suffer from a genetic mitochondrial disease. Genetic mitochondrial diseases often present in early childhood and lead to severe symptoms, such as mental retardation, heart failure and rhythm disturbances, dementia, movement disorders, stroke-like episodes, deafness, blindness, limited mobility of the eyes, vomiting and seizures.

About KL1333

KL1333 is a potent modulator of the cellular levels of NAD⁺, a central co-enzyme in the cell's energy metabolism. KL1333 has in preclinical models been demonstrated to increase mitochondrial energy output, reduce lactate accumulation, diminish the formation of free radicals and to have long-term beneficial effects on energy metabolism such as the formation of new mitochondria. It is in clinical development stage intended to document the use for chronic oral treatment in primary genetic mitochondrial disorders such as MELAS, KSS, PEO, Pearson and MERRF. KL1333 is currently being evaluated in clinical phase I studies and has been granted orphan drug designation in both the United States and Europe. KL1333 has been in-licensed from Yungin Pharm, a Korean pharmaceutical company.

About NeuroVive

NeuroVive Pharmaceutical AB is a leader in mitochondrial medicine, with one project in clinical phase I (KL1333) for genetic mitochondrial diseases and one project in preparation for a clinical phase II efficacy study for the prevention of moderate to severe traumatic brain injury (NeuroSTAT®). The R&D portfolio also consists of projects for genetic mitochondrial disorders, NASH and cancer. The company advances drugs for rare diseases through clinical development into the market, with or without partners. For projects for common indications the goal is out-licensing in the preclinical phase. A subset of compounds under NeuroVive's NVP015 program has been licenced to Fortify Therapeutics, a BridgeBio company, for local treatment development of Leber's Hereditary Optic Neuropathy (LHON). NeuroVive is listed on Nasdaq Stockholm, Sweden (ticker: NVP). The share is also traded on the OTCQX Best Market in the US (OTC: NEVPF).