

Press release

NeuroVive Pharmaceutical AB (publ)
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NeuroVive completes recruitment in the second part of its ongoing KL1333 clinical Phase Ia/b study

Lund, Sweden, 20 December 2019, NeuroVive Pharmaceutical AB (Nasdaq Stockholm: NVP, OTCQX: NEVPF) today announced the completed recruitment of healthy volunteers in the second part of the company's ongoing Phase Ia/b clinical study with candidate drug KL1333, in development for chronic oral treatment of primary mitochondrial disease.

The first part of the study, in which the effect of food intake on the uptake of KL1333 after a single dose had been assessed in healthy volunteers, showed promising drug properties and safety data. In the second part of the study, five cohorts of healthy volunteers received multiple ascending doses.

After evaluation of results from the two first parts of the study, the third and final part will be initiated. In this part, repeated doses of KL1333 will be given to patients with primary mitochondrial disease.

"We look forward to be able to start the exciting final part of the study where KL1333 for the first time will be given to patients with primary mitochondrial disease", said Magnus Hansson, Chief Medical officer and Vice President Preclinical and Clinical Development at NeuroVive.

The focus of the ongoing study, conducted in the UK, is to evaluate safety and pharmacokinetics of KL1333. In addition, biomarkers and functional measures will be assessed.

"During the first half of next year we also plan to initiate a natural history study in primary mitochondrial disease patients as part of our Phase II program, as a bridge to our clinical efficacy study, to optimize the patient selection criteria and use of endpoints. These are important steps in the opportunity of developing KL1333 towards a life changing treatment for patients with primary mitochondrial disease", said NeuroVive's CEO Erik Kinnman.

The information was submitted for publication, through the agency of the contact person set out below, at 3:15 p.m. CET on 20 December 2019.

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About primary mitochondrial diseases

Primary 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 primary mitochondrial disease. Primary 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. The candidate drug is intended for chronic oral treatment of primary 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 Yungjin 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 chronic treatment of primary mitochondrial diseases and one project, in preparation for clinical trials (NV354), for treatment of primary mitochondrial diseases with Complex I deficiency. NeuroSTAT for traumatic brain injury (TBI) is ready to enter a clinical phase II efficacy study. The R&D portfolio also consists of early projects for primary mitochondrial disease, and NASH. NeuroVive's ambition is to take drugs for primary mitochondrial diseases through clinical development and all the way to market, with or without partners. For the TBI and NASH projects the goal is to enter strategic partnerships. 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).