

## Press release

NeuroVive Pharmaceutical AB (publ)  
556595-6538



### NeuroVive receives KL1333 clinical trial regulatory approval

*Lund, Sweden, 10 October 2018* - **NeuroVive Pharmaceutical AB (Nasdaq Stockholm: NVP, OTCQX: NEVPF) today announced that it has received approval of its clinical trial application concerning a planned phase I KL1333 study in patients and healthy volunteers from the UK regulatory authority, Medicines and Healthcare products Regulatory Agency (MHRA).**

KL1333 is a first-in-class NAD<sup>+</sup> modulator in clinical development for chronic oral treatment in genetic mitochondrial diseases.

The primary purpose of the study is to investigate the pharmacokinetics, safety and tolerability of KL1333 in healthy volunteers and thereafter in patients with genetic mitochondrial disease. The study will be conducted in the UK and is planned to start in Q4 2018.

The study includes an assessment of a single dose in healthy volunteers, to bridge to the previously conducted single ascending dose study in South Korea, completed earlier this year, and furthermore an assessment of the effect of food intake. The study will also include a multiple ascending dose part in healthy volunteers, and in patients with genetic mitochondrial disease.

“MHRA approval is an important milestone ahead of the initiation of our study. It also verifies the quality of the work we have done during the planning and design stage. The study will bring us an important step closer to our goal of bringing a novel treatment opportunity to patients with severe mitochondrial disease with few or no treatment options,” said Magnus Hansson, Chief Medical Officer and Vice President Preclinical and Clinical Development at NeuroVive.

*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 08.30 a.m. CEST on 10 October 2018.*

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## **About KL1333**

KL1333 is a potent modulator of the cellular levels of NAD<sup>+</sup>, 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 Yungjin Pharm, a South Korean pharmaceutical company.

## **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 syndromes. An estimated 12 in every 100,000 people suffer from a mitochondrial disease. 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, droopy eyelids, limited mobility of the eyes, vomiting and seizures.

## **About NeuroVive**

NeuroVive Pharmaceutical AB is a leader in mitochondrial medicine, with one project in clinical phase II development for the prevention of moderate to severe traumatic brain injury (NeuroSTAT<sup>®</sup>) and one project in clinical phase I (KL1333) for genetic mitochondrial diseases. The R&D portfolio also consists of projects for genetic mitochondrial disorders, cancer and NASH. The company advances drugs for rare diseases through clinical development into the market. 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).