Press release
NeuroVive Pharmaceutical AB (publ)
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NeuroVive and Yungjin reports positive KL1333 phase I clinical study results paving the way for further clinical development

Lund, Sweden and Seoul, Korea, 21 May 2018 – NeuroVive Pharmaceutical AB *(Nasdaq Stockholm: NVP, OTCQX: NEVPF) and Yungjin Pharm Corporation Ltd (South Korea Stock Market, KRX 003520) today jointly announced positive topline results after data base lock in the phase I single ascending dose (SAD) clinical study of KL1333, a novel treatment in clinical development for orphan genetic mitochondrial diseases.*

Review of the topline phase I data shows that KL1333 has a highly favourable and very clear dose-proportional pharmacokinetic (PK) profile. There were no serious adverse events (SAEs), and only mild gastrointestinal adverse events (AEs) were recorded at higher doses. Based on the positive PK and safety results NeuroVive is moving rapidly to initiate the next study in Europe that will include repeated dosing (multiple ascending dose; MAD) in healthy volunteers and patients. Detailed analysis of the complete data set is ongoing.

There is a huge unmet medical need for medicines that treat genetic mitochondrial diseases. Patients can have severe symptoms in any organ and have significantly reduced life-expectancy. These diseases are rare diseases for which there are almost no registered medicines.

“We are very excited about the results from the first in human clinical trial of KL1333 and see them as clearly promising for the continued clinical development of this important program together with NeuroVive,” commented Yungjin Pharm CEO & President Chae J. Lee.

NeuroVive will now, together with a leading global contract research organization (CRO), rapidly progress the planning and preparation of the phase I MAD study of KL1333 in healthy volunteers and genetic mitochondrial disease patients. The study is expected to commence in the second half of 2018.

“With the convincing safety profile of KL1333 and favorable PK data, we will confidently bring this promising program forward in development with the highest priority. The next important step is the clinical phase I MAD study, which will take us further towards the goal of offering a novel treatment to patients with severe genetic mitochondrial disease with few or no treatment options,” said NeuroVive CEO Erik Kinnman.

The MAD study will consist of two parts; a dose escalation in healthy volunteers, and also multiple dosing of patients with genetic mitochondrial disease. The purpose of the study is to further investigate safety and pharmacokinetics of KL1333 prior to initiating a phase II efficacy clinical trial. The study will be conducted at sites in the UK and results are expected in the first half of 2019.

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 11:00 a.m. CEST on 21 May 2018.

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About the KL1333 SAD study
The study is a dose block-randomized, double-blind, placebo-controlled, single-dose, dose-escalation, phase I clinical study. 25 ,50, 100, 400, 600, 800 mg of KL1333 was administered in 60 healthy volunteers to investigate pharmacokinetics, safety and tolerability.

About KL1333
KL1333 is a potent modulator of the cellular levels of NAD+, a central coenzyme 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.

About genetic mitochondrial disease
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 stunted growth, 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®) and one project in clinical phase I (KL1333) for genetic mitochondrial diseases. The R&D portfolio consists of several late stage research programs in areas ranging from genetic mitochondrial disorders to cancer and metabolic diseases such as NASH. The company's strategy is to advance drugs for rare diseases through clinical development and into the market. The strategy for projects within larger indications outside the core focus area is out-licensing in the preclinical phase. NeuroVive is listed on Nasdaq Stockholm, Sweden (ticker: NVP). The share is also traded on the OTCQX Best Market in the US (OTC: NEVPF).

About Yungjin Pharm
Yungjin Pharm Co. Ltd., established in 1952, has been playing a major role as a forerunner in the Korean pharmaceutical industry for half a century. With the inspiring mission statement, "To relieve the suffering of mankind from diseases with our innovative, effective and safe pharmaceutical products", they have shown a successful contribution not only within Korea, but also through global expansion. As a result, they have received a total of 25 awards including the President Award for Superior Product Development, the Prime Minister Award, Industry Award and many more. These accomplishments demonstrate their sustainability and commitment to the development of innovative products and business excellence in both overseas and domestic segments. The company is listed on the South Korean stock market, KOSPI (KRX 003520).