



Press release

NeuroVive Pharmaceutical AB (publ) 556595-6538

# NeuroVive and Yungjin Pharm start clinical development in genetic mitochondrial disease

*Lund, Sweden and Seoul, South Korea, 27 June 2017* - *NeuroVive Pharmaceutical AB (Nasdaq Stockholm: NVP, OTCQX: NEVPF) and Yungjin Pharm Corporation Ltd (South Korea Stock Market, KRX 003520) today announced that the clinical phase I study of KL1333 has started in Korea and that the first healthy volunteer has been enrolled.* 

The study is a double-blind, placebo-controlled, single-dose, dose-escalation phase I clinical study to investigate the pharmacokinetics and safety/tolerability of KL1333 in healthy subjects. The study is planned to encompass a total of 60 healthy volunteers and will be fully performed by Yungjin Pharm. KL1333 is in development for the treatment of genetic mitochondrial diseases, such as MELAS and Kearns-Sayre syndrome, for which there are no current medicines.

"This is a valuable milestone in our goal to offer patients with genetic mitochondrial disease a new treatment option. Furthermore, it is an important starting point in our collaboration with Yungjin Pharm", said Erik Kinnman, CEO of NeuroVive.

"We visited the clinical site just a couple a weeks ago and were very impressed by their extensive experience and professionalism in handling early clinical phase studies", said Magnus Hansson, Chief Medical Officer of NeuroVive.

The principal investigator for the study is Professor Kyung-Sang Yu MD, PhD at the Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine.

"We are excited about the collaboration with NeuroVive, and the initiation of this clinical program is a significant step forward in the development of innovative medicines in this area with great medical needs", Su Jun Park, CEO of Yungjin Pharm.

On 2 May 2017, Yungjin Pharm granted NeuroVive exclusive global rights to develop and commercialize KL1333, except in Korea and Japan, where Yungjin Pharm retains full rights. Both companies will continue to develop KL1333 in their respective markets, primarily for the treatment of genetic mitochondrial disorders. NeuroVive plans to initiate a complementary European and/or US based phase I study in early 2018.

For further information about the study, please visit: https://clinicaltrials.gov/ct2/show/NCT03056209

**For investor relations and media questions, please contact:** Cecilia Hofvander, NeuroVive, Tel: +46 (0)46 275 62 21 or <u>ir@neurovive.com</u>

**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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#### Notes to editors

#### About KL1333

KL1333 is a potent modulator of the cellular levels of NAD<sup>+</sup>, a central coenzyme in the cell's energy metabolism. KL1333 has in preclinical studies 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. It is in clinical development stage for chronic oral treatment of primary genetic mitochondrial disorders such as MELAS, KSS, CPEO, PEO, Pearson, MERRF and Alpers syndrome. Its mode of action is complementary to that of NVP015, which is intended to alleviate acute episodes of energy crises in genetic mitochondrial disorders with dysfunction in respiratory complex I and to NVP025, intended to protect the mitochondria in skeletal muscle from dysfunctional calcium handling and consequential muscle wasting.

# **About Mitochondrial Diseases**

Approximately 12 in every 100,000 people suffer from a genetic mitochondrial disorder. Mitochondrial disorders usually present in early childhood. KL1333 qualifies for orphan drug designation in the US and Europe during clinical development, enabling a faster and less costly route to market, and a higher price. In 2016, the orphan drug market amounted to USD 114 billion and in the same year, the average annual cost for the treatment of a single patient was an estimated USD 140,443 (approx. 1.3 million SEK).<sup>1</sup>

<sup>1</sup> Evaluate Pharma Orphan Drug Report 2017

# **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*).

# **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). The R&D portfolio consists of several late stage research programs in areas ranging from genetic mitochondrial disorders to cancer and metabolic diseases

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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).

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 above, at 10:30 a.m. CEST on 27 June 2017.