

Press release

NeuroVive Pharmaceutical AB (publ)
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NeuroVive reports promising progress in its clinical project for genetic mitochondrial diseases, KL1333

Lund, Sweden, 11 December 2017 – NeuroVive Pharmaceutical AB (Nasdaq Stockholm: NVP, OTCQX: NEVPF) and Yungjin Pharm today announced that the phase I clinical study in Korea within the companies' joint project KL1333, an investigational treatment for genetic mitochondrial disorders, including MELAS (Mitochondrial Myopathy, Encephalopathy, Lactic Acidosis and Stroke-like episodes), is proceeding according to plan.

The first part of the study has been successful. The pharmacokinetic data was in line with expectations and no adverse safety signals were detected. The study's remaining higher dose-cohorts have now been approved by the Korean medicinal authority, the Ministry of Food and Drug Safety (MFDS).

"We are very excited about the progress of the first KL1333 clinical study. Along with the recent positive opinion on European orphan drug designation, it brings us one step closer to initiating our own clinical phase Ib study, and to our ultimate goal of providing a treatment opportunity to patients with different genetic mitochondrial disorders, where there is a high medical need and in most cases no specific treatments available," commented Magnus Hansson, M.D., Ph.D., Chief Medical Officer and VP of Preclinical and Clinical Development at NeuroVive.

The study is a double-blind, placebo-controlled, single-dose, dose-escalation phase I clinical study to investigate the pharmacokinetics, safety and tolerability of KL1333 in healthy volunteers. The first part of the study included dose levels of 25 mg and 50 mg. With both doses having been deemed safe, the MFDS has approved dose escalation and an updated study design. A multiple-dose, phase Ib study, sponsored by NeuroVive, is planned to be initiated in Europe and/or the U.S. in 2018.

"The results from the first part of the study are positive and the approval from the MFDS is of crucial importance for KL1333 and the continuation of its global development program. In close collaboration with our partner NeuroVive, we have a great possibility to develop KL1333 into a novel treatment opportunity for patients with genetic mitochondrial disorders, such as MELAS," said Soo-Hyun Lew, M.D. Executive Director of Development at Yungjin Pharm.

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. CET on 11 December 2017.

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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.otcmartets.com/stock/NEVPF/quote

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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 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, CPEO, PEO, Pearson and MERRF. 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 complex I and to NVP025, intended to protect the mitochondria in skeletal muscle from dysfunctional calcium handling and consequential muscle wasting.

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).