

Press release

NeuroVive Pharmaceutical AB (publ)
556595-6538



NeuroVive's KL1333 program granted orphan drug designation by the European Commission

Lund, Sweden, 13 December 2017 – NeuroVive Pharmaceutical AB (Nasdaq Stockholm: NVP, OTCQX: NEVPF), announced today that the European Commission has granted orphan drug designation (ODD) for the company's KL1333 program for oral treatment of the genetic mitochondrial disease *Mitochondrial Myopathy, Encephalopathy, Lactic acidosis and Stroke-like episodes (MELAS)*.

The decision by the Commission confirms the opinion previously issued by the European Medicine Agency's (EMA) Committee for Orphan Medicinal Products (COMP), which was communicated by NeuroVive on 8 November 2017. The orphan drug designation for KL1333, together with NeuroVive's status as a micro, small and medium-sized enterprise (SME), offers NeuroVive access to free scientific advice (protocol assistance) from the EMA, as well as fee reductions and further administrative assistance from EMA's SME office. If approved for orphan drug status when authorized for marketing, KL1333 would benefit from ten years of market exclusivity within the European Union.

KL1333 is being developed jointly by NeuroVive and the Korean pharmaceutical company Yungjin Pharm. KL1333 has shown promising results in preclinical models and a clinical phase I study is currently being conducted in Korea. NeuroVive plans to initiate the next clinical phase I study in 2018.

For more information, please contact:

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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 08:30 a.m. CET on 13 December 2017.

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

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.otcm Markets.com/stock/NEVPF/quote

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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®) 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).