NeuroVive's Clinical Development Project KL1333 Receives Positive Opinion on European Orphan Drug Designation

Lund, Sweden, 8 November 2017 – NeuroVive Pharmaceutical AB *(Nasdaq Stockholm: NVP, OTCQX: NEVPF), the mitochondrial medicine company, today announced that the Committee for Orphan Medicinal Products (COMP) at the European Medicines Agency (EMA) has provided a positive opinion on granting Orphan Drug Designation in the European Union for NeuroVive's KL1333 for oral treatment of the genetic mitochondrial disease Mitochondrial Myopathy, Encephalopathy, Lactic acidosis and Stroke-like episodes (MELAS).*

The European Commission will issue its formal decision based on the opinion approximately one month after the initial vote. Being granted orphan drug designation for KL1333 would offer NeuroVive, by being classified as a micro, small and medium-sized enterprise (SME), the possibility of receiving free scientific advice/protocol assistance and reduced fees for the marketing authorisation application. If approved for orphan drug status when authorised for marketing, KL1333 would be granted market exclusivity for ten years within the EU.

"The opinion from COMP strongly indicates that we may receive a positive formal decision from the Commission on granting orphan drug designation for KL1333 in Europe. This is an important milestone for NeuroVive, and the access to scientific advice and reduced fees from the EMA are both very valuable for the continued development and the orphan drug status that may follow will support the commercialisation of the project," said Erik Kinnman, CEO, NeuroVive.

KL1333 has been developed by the South Korean pharmaceutical company Yungjin Pharm and has in pre-clinical models shown to increase mitochondrial aerobic energy production, while limiting the accumulation of lactate, counteracting the formation of free radicals and lead to other long-term positive effects on energy metabolism such as the formation of new mitochondria.

On 2 May 2017, NeuroVive was granted exclusive rights from Yungjin Pharm to develop and commercialize KL1333 globally, except for in Korea and Japan where Yungjin Pharm keeps its exclusive rights. Both companies will develop KL1333 within their respective territories, simultaneously collaborating on an international level. The first clinical phase I studies have been initiated in South Korea and NeuroVive plans to start the next clinical phase I study in 2018.

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 8 November 2017.

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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 respiratory 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)*.