Press release
NeuroVive Pharmaceutical AB (publ)
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NeuroVive's KL1333 receives FDA Orphan Drug Designation for treatment of mitochondrial diseases

Lund, Sweden, 18 April 2018 NeuroVive Pharmaceutical AB *(Nasdaq Stockholm: NVP, OTCQX: NEVPF), the mitochondrial medicine company, today announced that it has been granted Orphan Drug Designation by the United States FDA Office of Orphan Products Development for its project KL1333 for treatment of inherited mitochondrial respiratory chain diseases (MRCD).*

Orphan drug designation (ODD) will give the KL1333 program extra access to regulatory and scientific advice and interactions at the FDA and may enable a focused development program and speedy approval process. ODD opens up for market exclusivity for seven years within US for NeuroVive´s KL1333, when authorised for marketing.

"The ODD approval by the US FDA is a validation of the quality of the KL1333 documentation to date and yet an important milestone for NeuroVive and the KL1333 project. The ODD will be beneficial to us in our efforts to rapidly document the effects and safety of KL1333 in genetic mitochondrial diseases and bring this novel treatment opportunity to the market and patients who are in great need of it," said Erik Kinnman, CEO, NeuroVive.

KL1333 has been developed by the South Korean pharmaceutical company Yungjin Pharm and has in pre-clinical models been 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.

NeuroVive was 2017 granted exclusive rights from Yungjin Pharm to develop and commercialize KL1333 globally, except in Korea and Japan where Yungjin Pharm retains its exclusive rights. The companies will develop KL1333 within their respective territories collaborating closely on an international level to utilize possibilities for synergies. The first clinical phase I study has recently recruited its last healthy volunteer and results are expected by June. NeuroVive plans to start the next clinical phase I multiple ascending dose study in the second half of 2018.

In the EU, Orphan Drug Designation has been obtained for the treatment of the genetic mitochondrial disease: Mitochondrial Myopathy, Encephalopathy, Lactic acidosis and Stroke-like episodes (MELAS).

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 09:15 a.m. CET on 18 April 2018.

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About KL1333 and the company's MRCD project portfolio
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 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).