

Press release

NeuroVive Pharmaceutical AB (publ)
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NeuroVive in-licenses a genetic mitochondrial disease clinical stage project from Yungjin Pharm

Lund, Sweden and Seoul, Korea, 2 May 2017 - NeuroVive Pharmaceutical AB (Nasdaq Stockholm: NVP, OTCQX: NEVPF) and Yungjin Pharm Corporation Ltd (South Korea Stock Market, KRX 003520) today jointly announced that they have entered into a global licensing agreement on Yungjin Pharm's compound KL1333 for genetic mitochondrial disorders. The in-licensed project is about to enter Phase I clinical development.

KL1333 is a drug intended for treatment of orphan genetic mitochondrial disorders. KL1333 acts through modulating the levels of NAD⁺ and thereby rectifying mitochondrial defects. Yungjin Pharm has received an IND and a clinical study approval in Korea, and the clinical study is scheduled to start within a couple of months.

Yungjin Pharm has granted NeuroVive exclusive global rights to develop and commercialize KL1333 worldwide, except for Korea and Japan, where Yungjin Pharm retains all commercial and marketing rights. Under the terms of the agreement, NeuroVive will pay Yungjin Pharm upfront payments of 1 million USD at signing, 1 million USD one year after the signing and an additional 1 million USD after the completion of a successful phase I clinical trial. Further payments will be paid upon successful achievement of clinical development (in total 12 MUSD) market and reimbursement approval (in total 42 MUSD) milestones. In addition, Yungjin Pharm will also be eligible to receive approval and sales milestone payments and tiered single to low double-digit royalties on future net sales. Both companies will develop KL1333 in their respective territories, primarily for the treatment of genetic mitochondrial disease.

“The NeuroVive team is extremely pleased to acquire the rights to the clinical stage candidate drug KL1333 for genetic mitochondrial disorders, an area of high unmet medical need. The project is a perfect fit with our existing project portfolio in mitochondrial disorders”, said Erik Kinnman, CEO at NeuroVive.

“The addition of KL1333 is perfectly in line with our business model focusing on the development of orphan indication project all the way to the market. We look forward to working with Yungjin Pharm on this opportunity, with the aim to bring relief to patients suffering from genetic mitochondrial diseases”, he continued.

NeuroVive will now initiate activities in preparation for the next clinical study in Europe and/or in the US.

“With NeuroVive’s specialist expertise in mitochondrial medicine and clinical development experience, we consider them an ideal partner for Yungjin Pharm, and with this agreement global development of KL1333 has been secured. It has been a pleasure working with NeuroVive in this process and we look forward to a fruitful collaboration”, said Sujun Park, CEO & President at Yungjin Pharm.

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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 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. It's 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.

A clinical trial application for a Korean Phase I study has been approved by Korean authorities and is scheduled to start within a couple of months, performed fully by Yungjin Pharm. NeuroVive plans to initiate a complementary European and/or US based phase I study in early 2018.

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).¹

¹ 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. The company is committed to the discovery and development of medicines that preserve mitochondrial integrity and function in areas of unmet medical need. 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 enhances the value of its projects in an organization that includes strong international partnerships and a network of mitochondrial research institutions, as well as expertise with capacities within drug development and production.

NeuroVive has a project in early clinical phase II development for the prevention of moderate to severe traumatic brain injury (NeuroSTAT®). NeuroSTAT has orphan drug designation in Europe and in the US.

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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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.

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