Press Release

NeuroVive Pharmaceutical AB (publ), 556595-6538
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NeuroVive clarifies strategy for NeuroSTAT

NeuroVive Pharmaceutical AB (Nasdaq Stockholm: NVP) today announced that it intends to initiate a process with the aim to transfer the rights to develop and commercialize its NeuroSTAT program into a new company based in the US. The effort is in line with NeuroVive's strategy to focus its resources on its primary mitochondrial disease (PMD) projects, KL1333 and NV354. The process will start immediately with the plan to, subject to funding, establish the new company (NewCo) during the second half of 2020.

The plan to transfer the NeuroSTAT assets to NewCo is a further step towards focusing the company towards its core primary mitochondrial disease programs (PMD), KL1333 currently about to enter into the patient part of the ongoing a Phase Ia/b study and preparing NV354 for a Phase I trial planned to start the first half of 2021. NeuroVive will license development and commercial rights for NeuroSTAT to the NewCo once established with the exception of rights for the Asian market, which will remain within NeuroVive Asia Ltd.

The purpose of establishing a NewCo is to increase the possibilities to create value in the Phase II ready NeuroSTAT clinical program in the US, where FDA has approved the IND and given the program a Fast Track designation.

"Management and the Board are convinced that given the focus on the PMD strategy, a spin out of NeuroSTAT may ensure value generation, for TBI patients, as well as for our shareholders. Through the increased focus on our PMD projects we can dedicate our resources and proceeds from the proposed rights issue on KL1333 and NV354", said Erik Kinnman, CEO at NeuroVive.

NeuroVive aims to appoint and work closely with appropriate US based advisors to optimize the incorporation of the NewCo as well as exploring a long-term funding strategy for NeuroSTAT.

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About NeuroSTAT

The aim for NeuroSTAT, which targets the mitochondria, is to counteract the emergence of neurological and functional secondary brain damage after a traumatic injury, and thereby establish a therapy that will lead to increased survival, improved quality of life and preserved neurological function. NeuroSTAT has shown favorable properties in a Phase II clinical study that investigated safety, tolerability, pharmacokinetics, i.e. the chemical metabolism, and passage to the brain, of two different doses of the active ingredient ciclosporin in patients with severe traumatic brain injury. Further, analyses of brain cell damage biomarkers in samples from the patients, gave a first signal of clinical effect. In addition, in advanced experimental TBI models at the University of Pennsylvania (Penn), a 35% decrease in volume of brain injury was observed after NeuroSTAT treatment, as well as positive changes in brain energy metabolite levels and mitochondrial respiratory function, together with decreased generation of reactive oxygen species. NeuroSTAT has orphan drug designation both in Europe and the US, as well as an IND approval for clinical development in the US. In addition, in July 2019, NeuroSTAT received Fast Track designation from the FDA.

About Us

NeuroVive Pharmaceutical AB is a leader in mitochondrial medicine, with one project in clinical phase I (KL1333) for chronic treatment of primary mitochondrial diseases and one project, in preparation for clinical trials (NV354), for treatment of primary mitochondrial diseases with Complex I deficiency. NeuroSTAT for traumatic brain injury (TBI) is ready to enter a clinical phase II efficacy study. The R&D portfolio also consists of early projects for primary mitochondrial disease, and NASH. NeuroVive's ambition is to take drugs for primary mitochondrial diseases through clinical development and all the way to market, with or without partners. For the TBI and NASH projects the goal is to enter strategic partnerships. A subset of compounds under NeuroVive's NVP015 program has been licenced to Fortify Therapeutics, a BridgeBio company, for local treatment development of Leber's Hereditary Optic Neuropathy (LHON). NeuroVive is listed on Nasdaq Stockholm, Sweden (ticker: NVP). The share is also traded on the OTC Market's Pink Open market in the US (OTC: NEVPF).

Image Attachments

Brain TBI

Attachments

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