# Pressmeddelande

NeuroVive Pharmaceutical AB (publ)
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## NeuroVive receives positive EMA Scientific Advice on its NeuroSTAT development plan for TBI

***Lund, Sweden, 21 September 2017 - NeuroVive Pharmaceutical AB*** *(Nasdaq Stockholm: NVP, OTCQX: NEVPF),* ***the mitochondrial medicine company,*** *today announced positive feedback on its requested Scientific Advice (Protocol Assistance)* ***from the European Medicinal agency (EMA), on the NeuroSTAT development plan for treatment of moderate to severe Traumatic Brain Injury (TBI), including the design of its planned*** *Phase IIb proof of concept* ***study.***

Following the top line results from the company's clinical phase IIa CHIC (Copenhagen Head Injury Ciclosporin) study, conducted at Rigshospitalet in Copenhagen, Denmark, and the positive results from the preclinical studies, done in collaboration with the University of Pennsylvania (Penn), USA, NeuroVive requested Scientific Advice with EMA on the continued clinical development program to bring NeuroSTAT to the market for treatment of moderate to severe TBI, including the design of the planned Phase IIb proof of concept study with NeuroSTAT.

The EMA Scientific Advice feedback is supportive of the novel design NeuroVive has proposed for its efficacy studies, including advanced imaging assessments of the protective effect of NeuroSTAT on brain cells. Furthermore, a subpopulation of the patient population will be selected with similar types of injury to the brain which facilitates evaluation of efficacy. NeuroSTAT has received orphan drug designation status (ODD) from both EMA and the U.S. Food and Drug Administration (FDA).

"The feedback from EMA is very encouraging in moving our development program forward effectively since the design of our innovative proof of concept study including the endpoints and patient population were endorsed. This will potentially be beneficial in bringing our new treatment opportunity, NeuroSTAT, to the TBI patients who need it. Moreover, the introduction of novel designs and measures may be useful in the development of other TBI clinical projects", said Magnus Hansson, Chief Medical Officer at NeuroVive.

"The positive response from EMA is an important and valuable validation of our NeuroSTAT clinical development program, which is helpful as we will now approach FDA for formal advice", said Erik Kinnman, CEO at NeuroVive. "We are also intensifying our efforts in forming strategic alliances and applying for supportive non-dilutive co-funding of the Phase IIb NeuroSTAT proof of concept clinical study as we continue to develop this novel treatment opportunity for patients with TBI, an area of high unmet medical need", he continued.

**For further information, please contact:**
Erik Kinnman, CEO NeuroVive, Tel: +46 (0)46 275 62 21 or ir@neurovive.com

**NeuroVive Pharmaceutical AB (publ)**
Medicon Village, SE-223 81 Lund, Sweden
Tel: +46 (0)46 275 62 20 (switchboard)
www.neurovive.com

### About TBI

Traumatic brain injury (TBI) is caused by external violence to the head resulting in immediate damage to nerve cells. The damage continues to worsen for several days after the trauma, which in many cases has a significantly negative effect on the overall injury. At present, there are no approved treatments for the prevention of these secondary injuries. In the US, some 2.2 million people are affected annually, causing more than 50,000 deaths and 280,000 hospitalizations. The direct and indirect costs associated with TBI are an estimated USD 60 billion, and a large number of patients suffer moderate to severe functional disabilities requiring intensive care and various forms of support (www.nih.gov). The aim is that better preventive therapies for secondary brain damage, such as NeuroSTAT, will lead to higher survival rates, and significantly improve quality of life and neurological function of patients post-TBI.

### About the Phase IIa clinical study, CHIC at Rigshospitalet in Copenhagen

The phase II CHIC (Copenhagen Head Injury Ciclosporin) study was an open label study. The primary objective with the study was to establish safety and to characterize the pharmacokinetic profile of two dosing regimens of NeuroSTAT in severe Traumatic Brain Injury (TBI) patients. In addition, exploratory measurements to evaluate the efficacy of NeuroSTAT at mitochondrial level, and studies on how NeuroSTAT affects various biochemical processes after a brain injury, were conducted. Principal Investigator for the study is Jesper Kelsen, MD, PhD, Specialist in Neurosurgery, Department of Neurosurgery, Rigshospitalet, Copenhagen University Hospital.

### About the TBI experimental studies at the University of Pennsylvania (Penn)

In collaboration with Penn, NeuroVive has evaluated the effect of NeuroSTAT in a non-clinical experimental TBI model. A total of three substudies have successfully been conducted and completed. Positive results from the first two substudies established the pharmacokinetic profile of NeuroSTAT in blood, CSF and brain in the disease model, and showed that NeuroSTAT dose-dependently crosses the blood-brain barrier. The third and final sub study evaluated several different efficacy parameters related to mitochondrial function and metabolism, as well as advanced translational brain imaging MR techniques important in the design of the next clinical study. Further analyses and additional data were presented at the 7th Annual Traumatic Brain Injury Conference in Washington, DC, US on 24-25 May and at the Annual National Neurotrauma Symposium, Neurotrauma 2017, in Snowbird, Utah, US, on 9-12 July 2017.

### 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).

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