

## Press release

NeuroVive Pharmaceutical AB (publ)  
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### NeuroVive's NeuroSTAT project receives FDA Fast Track designation

*Lund, Sweden, 27 July 2019, NeuroVive Pharmaceutical AB (Nasdaq Stockholm: NVP, OTCQX: NEVPF)* today announced that the company's candidate drug NeuroSTAT, in development for treatment of moderate to severe traumatic brain injury, TBI, has received Fast Track designation from the US Food and Drug Administration, FDA, facilitating its clinical development and path forwards to market.

NeuroSTAT's FDA Fast Track designation makes NeuroVive eligible, for example, for more frequent meetings and written communication with the FDA, continuous feedback on each section of its New Drug Application, NDA (for sale and marketing in the US), as well as the possibility to have its NDA reviewed within a shorter timeframe. Fast Track designated drugs address unmet medical needs in serious conditions, and the process is designed to facilitate accelerated drug development and, ultimately, to get new drugs to patients faster.

NeuroSTAT protects and stabilizes mitochondria and is in development for treatment of moderate to severe traumatic brain injury. It focuses on secondary brain cell damage that occurs after a head trauma. The candidate drug has previously been evaluated in a European clinical Phase II trial focused on safety, where analyses of brain cell injury biomarkers showed signals of clinical effect. In addition, in a clinically relevant experimental model, NeuroSTAT significantly reduced the volume of brain injury by 35%. NeuroSTAT has orphan drug designation in both Europe and the US.

"The Fast Track designation and the recently approved IND (Investigational New Drug) are tremendous successes for our candidate drug NeuroSTAT, and a significant external validation of its quality and potential to address a tremendous unmet medical need. This will strengthen our position in the field and give us an advantage in partnering discussions concerning our planned Phase II efficacy study", said NeuroVive's CEO Erik Kinnman.

*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 11:30 a.m. CEST on 27 July 2019.*

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## About TBI

Traumatic brain injury (TBI) is caused by external force to the head resulting in immediate damage to nerve cells. The damage continues to worsen for several days after the acute trauma. The most common causes for TBI are trips and falls, traffic accidents and assault and battery<sup>1)</sup>. With more than 50 million new cases occurring each year, TBI is estimated to cost the global economy nearly 400 billion dollars annually in direct and indirect healthcare costs<sup>2)</sup>. A large number of patients suffer moderate to severe functional disabilities requiring intensive care and various forms of lifelong support.

1) [www.internetmedicin.se/page.aspx?id=1178](http://www.internetmedicin.se/page.aspx?id=1178)

2) Maas A et al. Traumatic brain injury: integrated approaches to improve prevention, clinical care, and research. *The Lancet Neurology*. 2017 Nov; 16(12):987.

## About NeuroSTAT

The aim for NeuroSTAT, which targets mitochondria, is to prevent 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. 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 in both Europe and the US.

## About NeuroVive

NeuroVive Pharmaceutical AB is a leader in mitochondrial medicine, with one project in clinical Phase I (KL1333) for genetic mitochondrial diseases and one project in preparation for a clinical Phase II efficacy study for the prevention of moderate to severe traumatic brain injury (NeuroSTAT®). The R&D portfolio also consists of projects for genetic mitochondrial disorders, NASH and cancer. The company advances drugs for rare diseases through clinical development into the market, with or without partners. For projects for common indications the goal is out-licensing in the preclinical phase. 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 OTCQX Best Market in the US (OTC: NEVPF).