Press release

NeuroVive Pharmaceutical AB (publ)
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NeuroVive's IND for clinical development of NeuroSTAT approved by FDA

Lund, Sweden, 10 May 2019, **NeuroVive Pharmaceutical AB** *(Nasdaq Stockholm: NVP, OTCQX: NEVPF)* **today announced that the US Food and Drug Administration, FDA, has approved NeuroVive's IND (Investigational New Drug) application, enabling clinical studies in the US with the company's drug candidate NeuroSTAT in development for treatment of moderate to severe traumatic brain injury, TBI.**

In the US, an FDA approved IND application is needed in order for not yet marketed investigational drugs to be used in clinical studies. The application has to contain detailed information about pharmacology and toxicology studies, manufacturing information, protocols for proposed clinical studies and information on the qualifications of the clinical investigators, to assure that research subjects will not be subjected to unreasonable risk.

"We're truly excited about the approved IND, which is also NeuroVive's first. It's a highly important milestone and a great recognition for the project, and also valuable in our discussions with possible external partners regarding non-dilutive funding and the continued development of NeuroSTAT," said NeuroVive's CEO Erik Kinnman.

NeuroSTAT's safety, tolerability and pharmacokinetic profile have previously been evaluated in a phase II clinical study in Copenhagen (the CHIC study). Samples from the patients were also analyzed for brain cell damage biomarkers which gave a first signal of clinical effect. NeuroSTAT has orphan drug designation in both Europe and the US.

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 08:30 a.m. CEST on 10 May 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.[1)] 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.[2)] 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
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 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 been evaluated in a Phase II clinical study (Copenhagen Head Injury Ciclosporin-CHIC) at Copenhagen University Hospital in Denmark. The study, which ended in May 2017, studied safety, tolerability and pharmacokinetics, i.e. the effect of two different doses of the active ingredient ciclosporin, as well as passage to the brain in patients with severe traumatic brain injury. In addition, samples from the patients have been included in a study where brain cell damage biomarkers have been analyzed. The protective effects in traumatic brain injury and the relationship between efficacy and drug concentrations in the brain, were also assessed in an experimental study at the University of Pennsylvania (Penn).

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).