NeuroVive receives positive FDA feedback on its NeuroSTAT TBI development plan

Lund, Sweden, 6 September 2018 - **NeuroVive Pharmaceutical AB** *(Nasdaq Stockholm: NVP, OTCQX: NEVPF)* **today announced positive U.S. Food and Drug Administration (FDA) feedback on its NeuroSTAT clinical development plan for the treatment of moderate to severe Traumatic Brain Injury (TBI) at a pre-IND (Investigational New Drug) meeting. The main feedback requested was on the design of the planned NeuroSTAT Phase II proof of concept TBI study.**

The FDA Formal Advice feedback supports the novel design proposed for the planned Phase IIstudy. The design includes, as an important endpoint, 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 brain injury which will simplify the evaluation of efficacy in the study. The next step in the regulatory process, ahead of the start of the study, is the submission and approval of an IND application that will enable clinical studies with NeuroSTAT in the US.

"The positive input from the FDA is welcomed and greatly helps us in the preparation of our important clinical efficacy study with NeuroSTAT in TBI patients. The selected, and now supported, endpoint, together with the relatively homogenous subpopulation of the planned study is innovative and gives us a good opportunity to show an effect in the planned study. This will give us the possibility to progress the NeuroSTAT clinical program further towards our goal of delivering a medicine that improves the outcome of patients following TBI," commented Magnus Hansson, Chief Medical Officer and VP of Preclinical and Clinical Development at NeuroVive.

NeuroSTAT has earlier received orphan drug designation (ODD) from both the FDA and the European Medicinal Agency (EMA). NeuroVive has also partnered with TRACK-TBI, a network of leading TBI researchers in the US with the mission to improve clinical trials in TBI.

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 6 September 2018.

For more information please contact:
Catharina Johansson, CFO, IR & Communications
+46 (0)46-275 62 21, ir@neurovive.com

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

About traumatic brain injury (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 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
NeuroVive's candidate drug for TBI treatment, 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 on circulation in the body and passage to the brain in patients with severe traumatic brain injury. The protective effects in traumatic brain injury and the relationship between effcacy and drug concentrations in the brain, were also assessed in an experimental study at the University of Pennsylvania (Penn). The NeuroSTAT candidate drug 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 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 also consists of projects for genetic mitochondrial disorders, cancer and NASH. The company advances drugs for rare diseases through clinical development into the market. 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).