

# Press release

NeuroVive Pharmaceutical AB (publ)  
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## NeuroVive presents TBI clinical study results at Nordic Neurotrauma Conference

**Lund, Sweden, 15 November 2017 – NeuroVive Pharmaceutical AB (Nasdaq Stockholm: NVP, OTCQX: NEVPF)** today announced that the company will present data from its clinical phase IIa study on traumatic brain injury (TBI), Copenhagen Head Injury Ciclosporin Study (CHIC), at the Nordic Neurotrauma Conference (NNC) in Lund, Sweden. The results will be presented at the NNC today by the study's Principal Investigator, Dr. Jesper Kelsen at the Department of Neurosurgery at Rigshospitalet in Copenhagen, Denmark.

The study, which includes evaluation of pharmacokinetic parameters and safety in a TBI-population, is NeuroVive's first patient study with NeuroSTAT. NeuroVive has previously presented topline results from the study, which indicated that adequate, dose-dependent concentration levels can be measured in blood samples and that NeuroSTAT reaches its target organ, the central nervous system (CNS). Furthermore, the results showed no unexpected safety signals. The detailed additional analysis of the data to be presented by Dr. Kelsen confirm the previous topline results.

"We very importantly reached the study's primary objectives: to demonstrate safety and to clarify the pharmacokinetics of NeuroSTAT at two separate dose levels (5 and 10 mg/kg/day) in patients with severe TBI. The 5-day continuous infusion of NeuroSTAT resulted in predictable blood concentrations of ciclosporin and cerebrospinal fluid measurements confirmed that it reaches the brain," said Dr. Jesper Kelsen, M.D., Ph.D., at the Department of Neurosurgery at Rigshospitalet in Copenhagen, Denmark, and the CHIC study's Principal Investigator.

"This is an important milestone in the NeuroSTAT program which enables us to proceed as planned to develop a new treatment for patients with severe brain injuries where there is a large unmet medical need. Brain injuries cause significant personal suffering to patients and relatives, and a huge direct and indirect cost to society. The need to advance care in this area is highlighted by the gathered international experts here at the NNC," commented Magnus Hansson, M.D., Ph.D., Chief Medical Officer, NeuroVive.

NeuroVive is also a proud sponsor of the Bertil Romner Award, a prize awarded at the NNC in memory of the neurosurgeon Bertil Romner, a pioneer and a visionary in neurotrauma research. Bertil Romner and NeuroVive designed the CHIC study, and he served as the study's initial Principal Investigator. The prize is awarded an abstract of particular scientific value, presented at the conference with clarity and enthusiasm.

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**NeuroVive Pharmaceutical AB (publ)** - the mitochondrial medicine company. The company is listed on Nasdaq Stockholm, Small Cap, under the ticker symbol NVP. The share is also traded on the OTC Markets Group Inc market in the US. NeuroVive Pharmaceutical (OTC: NEVPF) trades on the OTCQX Best Market. Investors can find Real-Time quotes and market information for the company at [www.otcmarkets.com/stock/NEVPF/quote](http://www.otcmarkets.com/stock/NEVPF/quote)

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## 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 Nordic Neurotrauma Conference (NNC)

The NNC, hosted by the Scandinavian Neurotrauma Committee (SNC), is a multidisciplinary meeting place for clinicians and researchers interested in the exciting field of neurotrauma. Neurotrauma injuries are still amongst the most common indications to seek emergency care and account for the highest mortality in younger adults. The brain is still relatively poorly understood and current efforts aim to improve our understanding of the mechanisms and care of brain injuries.

## 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](http://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 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).