

## NEWS RELEASE

NeuroVive Pharmaceutical AB (publ)  
556595-6538

14 August 2014



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### Enrollment to phase II study on NeuroSTAT® continues

*Enrollment to the ongoing clinical phase IIa study with NeuroVive's drug candidate NeuroSTAT® for treating patients with severe traumatic brain injury (TBI) is continuing, and another two patients have been enrolled. Accordingly, at present, seven of a total of 20 patients have been enrolled in the study.*

The enrollment of new patients to the study has taken somewhat longer time than scheduled, but NeuroVive assumes that the ten patients to be treated with a lower dose will have been enrolled by year-end, or during Q1 2015 at the latest. Subsequently, the plan is to conduct interim analysis of data from these first ten patients with the aim of forming an opinion of treatment safety. If there are no safety concerns, the objective is for another ten patients to be enrolled during 2015 with treatment at a higher dose. In addition to planned interim analysis, continuous assessment treatment safety is being conducted. Based on safety assessments of the first patients, treatment with NeuroSTAT at the lower dose is considered to be safe and patient enrollment is continuing as planned.

This phase IIa study is an open, non-comparative study involving a total number of 20 patients. Its primary endpoint is to evaluate NeuroSTAT's® pharmacokinetics<sup>1</sup> and safety in TBI. Secondly, a number of measurements will be conducted, firstly to study NeuroSTAT's® efficacy at the mitochondrial level, and to study how biochemical processes are affected by NeuroSTAT® post-TBI. TBI is a segment subject to a major medical need, where there are no registered pharmaceutical therapies at present.

#### **About NeuroVive Pharmaceutical**

NeuroVive Pharmaceutical AB (publ), a leading mitochondrial medicine company, is developing a portfolio of products to treat acute cardiovascular and neurological conditions through mitochondrial protection. These medical conditions are characterized by a pressing medical need and have no approved pharmaceutical treatment options at present. NeuroVive's products CicloMulsion® (heart attack) and NeuroSTAT® (traumatic brain injury) are currently being evaluated in phase III and phase II studies, respectively. NeuroVive's research programs also include products for the treatment of anti-viral indications (Hepatitis B/C), brain cell injury in stroke patients, and drug candidates for cellular protection and treating mitochondria-related energy regulation diseases. NeuroVive's shares are listed on NASDAQ OMX, Stockholm, Sweden. The share is also traded on the OTC market in the US, under the NEVPF ticker symbol.

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<sup>1</sup> Pharmacokinetics is the study of a pharmaceutical's transformation in the body, i.e. how content of the pharmaceutical in the body changes through absorption, distribution, metabolism and excretion.

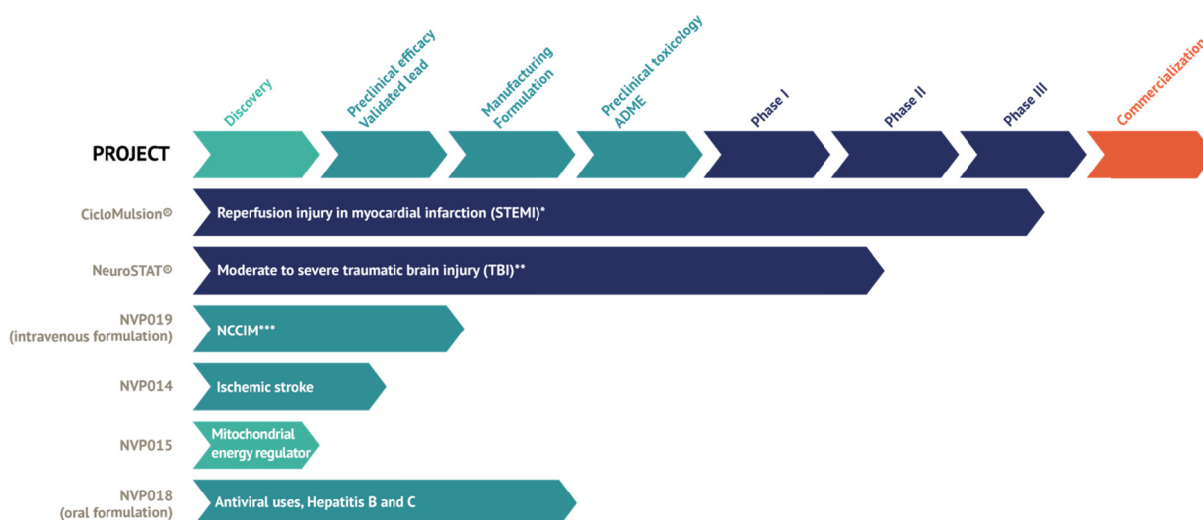
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### Current status of NeuroVive's products



\* Ongoing clinical external phase III study in the EU. Planning of phase III study in China started.

\*\* Clinical phase I study completed. Ongoing clinical phase II study in Copenhagen. Planning of international phase III study (EU, USA, China) started.

\*\*\* Non Cyclosporin Cyclophilin Inhibiting Molecules.

#### CicloMulsion®

NeuroVive's product CicloMulsion® is the first cyclophilin inhibitor developed for the treatment of reperfusion injury. The product's potential in the treatment of myocardial infarction is currently being evaluated in a clinical phase III study. The last of a total of 972 patients was enrolled on 16 February 2014. The results of the study are due to be announced in 2015 following the completion of the one-year follow-up of all patients and the analysis of the study data.

#### NeuroSTAT®

NeuroVive is developing NeuroSTAT® for the treatment of patients with severe traumatic brain injury. NeuroSTAT® is currently being evaluated in a clinical phase IIa study at Copenhagen University Hospital. The study focuses on safety and pharmacokinetics, and 7 of 20 planned patients have been enrolled so far. A phase III study is currently being planned and designed. NeuroVive has secured orphan drug designation for NeuroSTAT® for moderate and severe traumatic brain injury in the US and EU, which implies market exclusivity for seven years in the US and ten years in the EU, from the date NeuroVive obtains market authorization.

#### NVP018

NVP018 is NeuroVive's primary drug candidate in the company's new portfolio of potent cyclophilin inhibitors. These cyclophilin inhibitors, previously acquired, are part of a family of molecules known as Sangamides, whose molecular structures are based on a new and unique chemical platform of what are termed polyketides. It has undergone extensive pre-clinical development and has been developed for the treatment of Hepatitis B/C. The product has demonstrated high potency against virus replication and has a positive safety and pharmacokinetic profile. Cyclophilin inhibitors have broad-based applications and NeuroVive is currently evaluating NVP018's potential for other anti-viral indications.

#### NVP019

NVP019 is based on the same active compound as NVP018, and is being developed as the next generation of cyclophilin inhibitors to treat acute cardiovascular and neurological conditions, as well as for other acute cardiac conditions and acute conditions where general protection of vital organs is central to the course of the condition. An intravenous preparation will

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*be evaluated for these purposes in collaboration with external partners such as Hospices Civils de Lyon within the auspices of the OPeRA program.*

### **Other products**

*More information on all the products NeuroVive is developing is at <http://www.neurovive.se/index.php/en/research-development/research-overview>*

### **For Investor Relations and media questions, please contact:**

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It is also possible to arrange an interview with NeuroVive's CEO Mikael Brönnegård via the above contact.

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*NeuroVive Pharmaceutical AB (publ) is required to publish the information in this news release under The Swedish Securities Market Act. The information was submitted for publication on 14 August 2014, at 10:00 a.m. CET.*