## **NEWS RELEASE**

NeuroVive Pharmaceutical AB (publ) 556595-6538

4 June 2014



# NeuroVive signs new agreement with Hospices Civils de Lyon

NeuroVive is extending its collaboration with Hospices Civils de Lyon (HCL) and Professor Ovize, which broadens the scope of NeuroVive's cardiovascular business area and creates the right conditions for the company to retain its leading position in mitochondrial medicine. The new collaboration agreement, designated OPeRA (Organ Protection & Replacement Institute), includes pre-clinical research and development programs as well as clinical phase II programs, providing NeuroVive with access to medical technology and patient groups for the evaluation of its drug candidates.

NeuroVive began its collaboration with HCL, and the ongoing phase III study in CicloMulsion in Europe, in 2011. Research into CicloMulsion's efficacy beyond the treatment of reperfusion injury following heart attack grew out of the concept of mitochondrial protection in connection with organ injury focusing on heart disease. The OPeRA program has received financial backing from the French government and from several industry players including NeuroVive and covers the period up until 2018. The program encompasses a number of different medical areas and is based on multidisciplinary programs in diabetes, metabolic disorders, transplantation, cardiovascular diseases, inflammatory conditions and infectious diseases.

By becoming an industrial partner in the OPeRA program, NeuroVive has secured access to a unique scientific platform in mitochondrial medicine where its already developed cyclophilin inhibitors such as CicloMulsion, and new drug candidates, can be studied in various animal models for efficacy against cardiovascular diseases before being tested in humans. The clinical studies program at HCL plans to study CicloMulsion in several phase II studies with the intention of generating proof of concept, i.e. demonstrating CicloMulsion's efficacy in a smaller patient group before a decision is made to move on to a larger phase II study. A number of phase II studies in CicloMulsion are scheduled in the period up until 2018.

The partnership under the OPeRA program not only gives NeuroVive the rights to the projects directly covered by the collaboration with HCL, but also provides access to research findings for potential commercial development across all areas of the program.

"The collaboration with HCL in Lyon has been extremely positive, and we now perceive commercial benefits from extending the number of indications in the cardiovascular area for CicloMulsion, based on a highly developed pre-clinical platform and the potential for completing several phase II studies," commented NeuroVive's CEO Mikael Brönnegård.

#### **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

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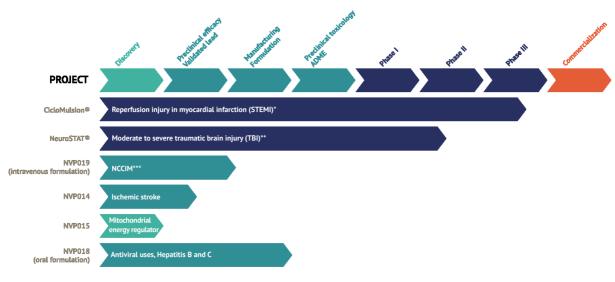
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cellular protection and treating mitochondria-related energy regulation diseases. NeuroVive's shares are listed on NASDAQ OMX, Stockholm, Sweden.

### 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 presentation 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 5 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

The recently acquired cyclophilin inhibitors are part of a family of molecules known as Sangamides, and are based on a new and unique chemistry platform of what are termed polyketides. NVP018 is NeuroVive's primary drug candidate in the company's new portfolio of potent cyclophilin inhibitors. 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.

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#### Other products

More information about all products developed by NeuroVive can be found at http://www.neurovive.se/index.php/en/research-development/our-products

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

Ingmar Rentzhog, Laika Consulting, Tel: +46 (0)46 275 62 21 or ir@neurovive.se It is also possible to arrange an interview with NeuroVive's CEO Mikael Brönnegård at the above contact.

# **NeuroVive Pharmaceutical AB (publ)**

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