

## NEWS RELEASE

NeuroVive Pharmaceutical AB (publ)  
556595-6538

26 May, 2015



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### **NeuroVive Asia signs collaboration agreement with Sanofi for the development and commercialization of CicloMulsion® in South Korea**

*NeuroVive Pharmaceutical AB (publ), the mitochondrial medicine company, announces that NeuroVive Pharmaceutical Asia group has signed a collaboration agreement with Sanofi's local affiliate for the development and commercialization of CicloMulsion® in South Korea. Under the agreement NeuroVive Asia will get an upfront payment, a conditional milestone payment and royalty on potential future sales in South Korea. CicloMulsion® is being developed for the treatment of reperfusion injury in cardiovascular disease.*

Sanofi is one of the largest global pharmaceutical companies with a prominent position in the expanding market for the treatment of cardiovascular disease. The agreement encompasses the registration, launch, promotion and sale of CicloMulsion® in South Korea.

The NeuroVive group is carrying out an extensive international program for the clinical development and commercialization of CicloMulsion® ahead of the product's potential market launch. The collaboration agreement between NeuroVive Pharmaceutical Asia Limited, a subsidiary of NeuroVive Pharmaceutical Asia, Inc., and Sanofi's local affiliate represents another step in this process. NeuroVive Pharmaceutical Asia, Inc. is a subsidiary of NeuroVive Pharmaceutical AB (publ).

"The collaboration with Sanofi will enable us to broaden the commercialization of CicloMulsion® for the treatment of cardiovascular disease. South Korea is an important market in Asia and this collaboration with Sanofi is further confirmation of CicloMulsion®'s clinical and commercial potential. I look forward to a long and productive partnership with Sanofi, with the aim of launching CicloMulsion® for the treatment of acute cardiovascular indications on the South Korean market," commented Mikael Brönnegård, NeuroVive's CEO.

CicloMulsion® is currently being evaluated for the treatment of reperfusion injury following myocardial infarct in a European clinical phase III study (the CIRCUS study). The product is also being evaluated for the treatment of other acute heart and kidney injuries within the framework of the collaboration with Hospices Civils de Lyon and in a clinical phase II study in collaboration with Skåne University Hospital in Lund, Sweden.

#### **Scope of the agreement**

Under the collaboration agreement, Sanofi's local affiliate will be responsible for regulatory processes and market approval, launch, marketing, distribution and sales of CicloMulsion® in South Korea. After its potential market launch, NeuroVive Pharmaceutical Asia will supply CicloMulsion® to Sanofi for distribution and sale in South Korea. NeuroVive Pharmaceutical Asia's remuneration comprises an upfront payment plus a conditional payment based on a pre-defined milestone. In addition, NeuroVive Pharmaceutical Asia will receive royalty based on potential future sales of CicloMulsion®.

Potential positive results from a planned Asian phase III study, alongside additional data from NeuroVive, including the results of the current European phase III study, will be used to seek market approval for CicloMulsion® in a number of Asian countries for the treatment of reperfusion injury following myocardial infarct. The planned Asian phase III study will be conducted by NeuroVive Asia

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alongside its collaboration partner Sihuan Pharmaceuticals in China and possibly other collaboration partners.

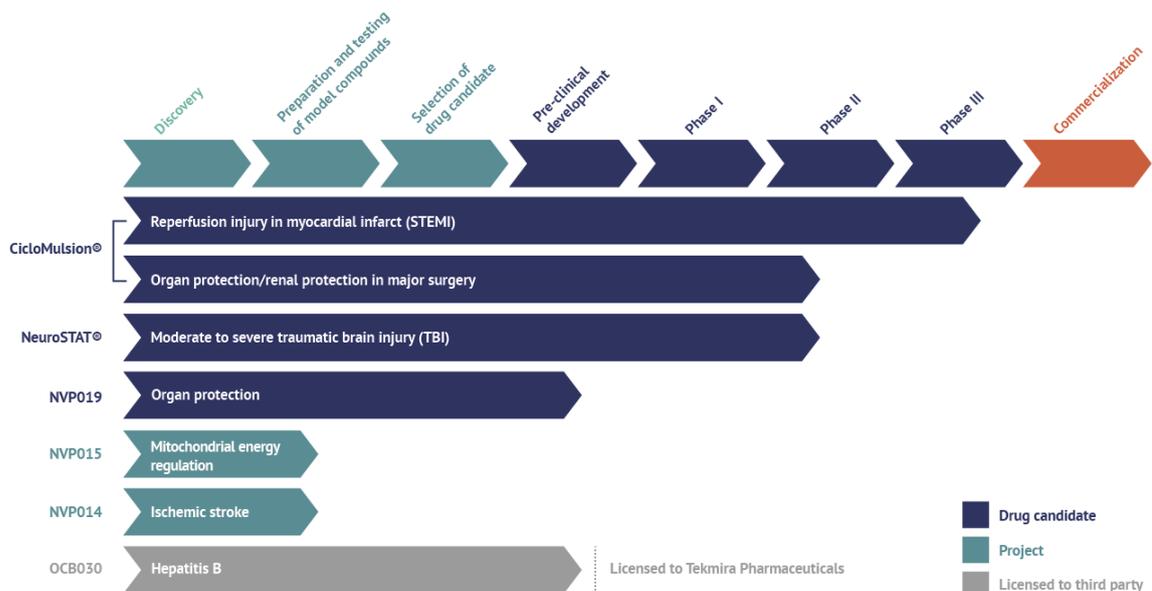
## Additional information about the agreement

The right to receive royalty under the agreement continues until the product is no longer sold in South Korea by Sanofi. The agreement term may be shorter should the agreement be terminated, for example if the product fails to demonstrate satisfactory efficacy, safety or commercial viability.

Remuneration received by NeuroVive Asia under the agreement will be included in NeuroVive's consolidated quarterly financial reports. Payments covered by the agreement are conditional on uncertain future events occurring. This means that should such events fail to materialise, such as if the product fails to demonstrate satisfactory efficacy or safety or commercial viability, the payments attributable to these events will not be made.

CicloMulsion® is in a clinical development phase, which means that the probability of reaching the market is dependent on a number of factors outside of NeuroVive's control. These include research-related and clinical risks such as the product failing to demonstrate satisfactory efficacy or safety during development, and regulatory risk in the form of regulatory authorities withholding market approval or pricing reimbursement or requiring an extension of or delay in the time required before the product can reach the market. There are numerous other circumstances attributable to the general development process, as for all products of a similar kind in clinical development. Investors are urged to evaluate the publicly available documents NeuroVive has published for further general information regarding the development of NeuroVive's products.

## Current status of NeuroVive's projects and drug candidates



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### **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 infarct is currently being evaluated in a clinical phase III study. The last of a total of 975 patients was enrolled on 16 February 2014. The final results of the analysis of the 12-month data are expected to be presented in the third quarter of 2015. CicloMulsion® is also being evaluated for the treatment of other acute heart and kidney injury within the framework of the collaboration with Hospices Civils de Lyon and in a clinical phase II study in collaboration with Skåne University Hospital in Lund, Sweden.

### **NeuroSTAT®**

NeuroVive is developing NeuroSTAT® for the treatment of patients with moderate or 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 10 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 cranial 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.

### **NVP019**

NVP019 is NeuroVive's primary drug candidate in the company's new portfolio of potent cyclophilin inhibitors belonging to a family of molecules known as Sangamides based on a new and unique polyketide engineering technology. NVP019 is being developed as the next generation cyclophilin inhibitor for the treatment of reperfusion injury in myocardial infarct, but also for other acute conditions where general protection of vital organs is central to preventing the progression of the disease. An intravenous formulation will be evaluated for this purpose in collaboration with external parties such as Hospices Civils de Lyon within the framework of the OPeRa program.

### **OCB030**

OCB030 is an oral formulation based on the same substance as NVP019. It has been developed for the treatment of Hepatitis B and was outlicensed to Tekmira Pharmaceuticals ([www.tekmira.com](http://www.tekmira.com)) in September 2014.

### **Other products**

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

### **About NeuroVive**

NeuroVive Pharmaceutical AB (publ), the 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® (myocardial infarct) 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 brain cell protection in stroke patients and drug substances for treating mitochondrial disorders causing energy deficiency. NeuroVive's shares are listed on NASDAQ OMX, Stockholm, Sweden.

### **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 or COO Jan Nilsson at 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 26 May 2015, at 10.15 a.m. CET.