

## NEWS RELEASE

NeuroVive Pharmaceutical AB (publ)  
556595-6538



9 September 2014

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### **NeuroVive signs \$150 million agreement with OnCore BioPharma for the outlicensing of NVP018 for the treatment of chronic Hepatitis B virus infection**

*NeuroVive Pharmaceutical AB, a leading mitochondrial medicine company, has signed an exclusive global outlicensing agreement with the US biotechnology company OnCore BioPharma, Inc. related to the development and commercialization of NeuroVive's drug candidate NVP018 for oral treatment of chronic Hepatitis B Virus (HBV) infection. The agreement can give NeuroVive in total \$150 million in conditional milestone payments plus royalties on future drug sales.*

"After extensive discussions with a number of leading pharmaceutical companies, I am delighted to announce that we have signed this agreement with OnCore, a strong partner that provides optimal resources to develop NVP018 from a stage of a promising drug candidate to a complete treatment for a global medical challenge. This confirms the financial potential inherent in our pharmaceuticals portfolio, and the revenues will allow us to further intensify our work in prioritized areas of mitochondrial medicine. I would also like to take the opportunity to put the spotlight on our COO Jan Nilsson, whose work has been critical to get this agreement in place," commented NeuroVive's CEO Mikael Brönnegård.

The licensing agreement provides OnCore with the exclusive global rights to develop oral formulations of NVP018 for the treatment of chronic Hepatitis B infection. The compensation to NeuroVive consists of an initial upfront payment plus a number of conditional payments based on pre-determined milestones and as well payments relating to sales targets. In addition, NeuroVive will receive incremental royalty payments based on gross revenue from future sales of NVP018. The total value of the agreement is \$150 million excluding royalty payments. The exact terms of the agreement regarding payments and royalty figures are not disclosed.

"OnCore stood out in the negotiations, which included several leading pharmaceutical companies, because of its exclusive focus on Hepatitis B and its plan to bring the drug candidate to market as quickly and efficiently as possible. In addition, the company's senior managers have delivered exceptionally strong results in the form of a pioneering treatment for Hepatitis C while working at Pharmasset. I am convinced that OnCore is the right collaboration partner for us," commented Jan Nilsson, NeuroVive's Chief Operating Officer.

"We perceive considerable potential in NVP018 and consider this agreement to be an important step towards developing a successful treatment for chronic Hepatitis B. Our objective is to cure chronic Hepatitis B, building on our success in Hepatitis C at Pharmasset." commented Dr. Michael Sofia, Chief Scientific Officer at OnCore.

#### **Cyclophilin inhibitors and NVP018**

NVP018 is an orally-available, sangamide-based, second generation cyclophilin inhibitor with a well-differentiated preclinical profile when compared to other cyclophilin inhibitors. Data presented in April at The International Liver Congress™ 2014, the annual meeting of the European Association for the Study of the Liver (EASL), showed that NVP018 appears to inhibit the Hepatitis B virus by two mechanisms in vitro. First, NVP018 directly inhibits several stages of viral replication in liver cells and second, NVP018 acts indirectly by strengthening the host immune response via interferon regulatory

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factors (IRFs), including potent inhibition of an interaction between cyclophilin A and IRF9, a key component of the Jak/Stat pathway that transports chemical signals through the cell membrane. Data also indicates that the risk of developing resistance, a significant clinical problem with current therapies for Hepatitis B, is very low with NVP018.

### **Hepatitis B—a global medical challenge**

Hepatitis B is a serious infection of the liver caused by the Hepatitis B virus (HBV) and is considered a major global health problem. Hepatitis B infection can cause chronic liver disease, which increases a patient's risk of death from liver cirrhosis and liver cancer. Estimates from the Centers for Disease Control and Prevention (CDC) indicate that up to 350 million people globally may be chronically infected with Hepatitis B and, according to the World Health Organization (WHO), more than 780,000 people die every year due to Hepatitis B. Most currently-available therapies aim to suppress this viral infection but do not lead to a cure in the overwhelming majority of patients. Identifying a functional or complete cure for Hepatitis B infection remains a significant area of unmet medical need.

### **About OnCore Biopharma**

OnCore Biopharma, Inc. is a privately held biotechnology company focused on the research, development, and commercialization of therapies for the treatment of chronic Hepatitis B virus (HBV) infection. The Company was founded by former executives of Pharmasset, Inc., which was acquired by Gilead Sciences in January 2012.

OnCore has assembled a portfolio of novel product candidates with unique mechanisms of action for the treatment of Hepatitis B and is focused on delivering a cure. It is widely believed that eradicating covalently closed circular DNA (cccDNA) in HBV-infected hepatocytes represents the ultimate solution for curing chronic Hepatitis B infected patients. OnCore is currently addressing an all-oral, permanent HBV cure by targeting cccDNA with the goal of achieving a "functional cure," wherein the risk of death from liver disease due to HBV is the same as a person with a naturally resolved infection. OnCore is combining agents against cccDNA with other novel direct acting antiviral mechanisms and strategies that engage host immune response. OnCore believes that combination therapy will be required to achieve complete eradication of HBV from the liver.

OnCore is located at the Pennsylvania Biotechnology Center in Doylestown, Pennsylvania, which is also home to the Hepatitis B Foundation and the Foundation's research center, the Baruch S. Blumberg Institute. For more information, please visit [www.oncorebiopharma.com](http://www.oncorebiopharma.com). To be added to the Company's e-mail list to receive news directly, please send an email to [ir@oncorebiopharma.com](mailto:ir@oncorebiopharma.com).

### **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 brain cell injury in stroke patients, and drug candidates for cellular protection and treating

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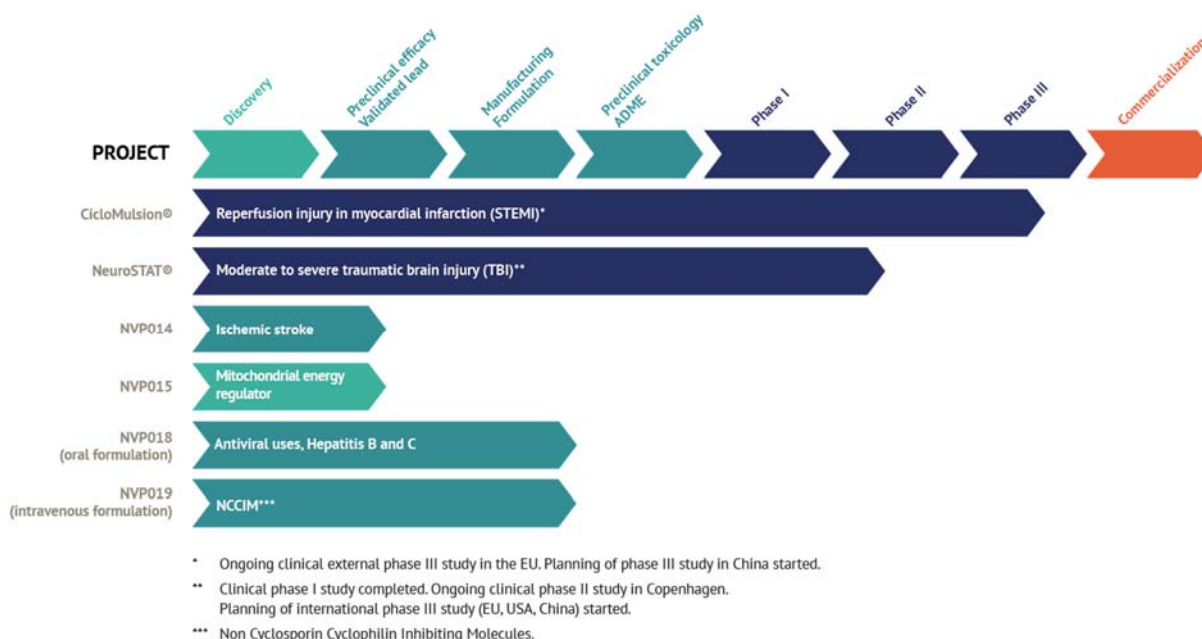
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mitochondria-related energy regulation diseases. NeuroVive's shares are listed on NASDAQ OMX, Stockholm, Sweden.

### Current status of NeuroVive's products



#### 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 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 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 belonging to a family of molecules known as Sangamides. Sangamides are analogs of the naturally-occurring polyketide Sanglifehrin A and are derived from a new and unique polyketide engineering technology. NVP018 has undergone extensive pre-clinical development for the treatment of chronic Hepatitis B and C and is outlicensed to OnCore Biopharma for further development and commercialization for the treatment of chronic Hepatitis B. The product has demonstrated high potency

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*against virus replication and has a positive safety and pharmacokinetic profile. Cyclophilin inhibitors potentially have a wide range of applications.*

### **NVP019**

*NVP019 is based on the same active substance as NVP018 and is being developed as the next generation cyclophilin inhibitor for acute heart and nerve cell damage, but also for other acute heart conditions and acute conditions where general protection of vital organs is central to 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.*

### **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>*

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

Ingmar Rentzhog, Laika Consulting, Tel: +46 (0)46 275 62 21 or [ir@neurovive.se](mailto:ir@neurovive.se)

It is also possible to arrange an interview with NeuroVive's COO Jan Nilsson or CEO Mikael Brönnegård 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 9 September 2014, at 8.00 a.m. CET.*