



NeuroVive and the European Brain Injury Consortium Sign TBI Clinical Trial Collaboration

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Phase II/III study will determine the safety and efficacy of NeuroSTAT® in patients with moderate to severe traumatic brain injury

Washington DC and Lund Sweden — March 3, 2011 — In advance of The Traumatic Brain Injury Conference in Washington, DC on March 7, NeuroVive is pleased to announce that it has signed an agreement with the European Brain Injury Consortium (EBIC) to conduct a European multi-center Phase II/III clinical trial of NeuroSTAT® for neuroprotection in patients with traumatic brain injury (TBI). The goal of the collaboration is to secure the highest possible study quality and compliance with clinical standards to support NeuroSTAT®'s rapid progress toward commercialization. To this end, NeuroVive will work closely with EBIC's key European experts in the field of neurotrauma and acute brain injuries.

NeuroVive will manage the study in close collaboration with the EBIC group and a clinical research organization (CRO) to be selected. The collaboration with EBIC includes development of the study protocol, site selection, patient recruitment, and statistical support. This adaptive design Phase II/III study will determine the safety and efficacy of NeuroSTAT® in moderate to severe TBI.

TBI is a leading cause of death and disability among a predominantly young male population, mostly victims of motor vehicle accidents. TBI is composed of two stages: a first stage of initial brain damage; and a second stage of mitochondrial collapse inside brain cells leading to additional cell death, brain damage and disability. The active agent in the NeuroSTAT® formula is a proven mitochondrial protector that in animal studies is a potent neuroprotectant against TBI. There are over 10 million TBI cases per year worldwide. Annually in the U.S., head trauma sends two million people to the emergency room and a half a million have injuries severe enough to be admitted to the hospital. TBI kills 50,000 people and leaves 80,000 people disabled. The annual market for an effective TBI drug is estimated to exceed US\$1 billion in the U.S. and Europe.

NeuroVive CEO Mikael Brönnegård comments:

"We are very pleased to collaborate on the NeuroSTAT® Phase II/III clinical trial with a highly respected organization like EBIC, comprising key opinion leaders and medical experts in the field of neurotrauma in Europe. Through this collaboration, we have an excellent opportunity to advance the development of NeuroSTAT® toward clinical use in treating millions of TBI patients worldwide."

Professor Andrew Maas, Chairman of EBIC, Professor and Chairman Department of Neurosurgery at University Hospital Antwerp, Belgium comments:

"This clinical trial is of great interest to us. The need for international collaboration in the conduct of research in the clinical management of head injury has never been greater, but



rigorous evaluation must be carried out on a range of approaches that include new pharmacological agents. Therefore, the collaboration with NeuroVive in conducting a clinical trial in TBI patients with their product NeuroSTAT® offers a unique way to address all critical issues in study design, selection of end-points, patient recruitment, study monitoring and, finally, study analysis.”

About NeuroSTAT®

NeuroVive conducts research and development of cyclosporin-based drugs, known as cyclophilin D inhibitors, to protect mitochondria in nerve cells. Mitochondrial collapse in nerve cells after the initial brain injury leads to additional cell death and brain damage. Protecting the mitochondria in nerve cells is a key emerging strategy in treating TBI by reducing overall damage and eventual disability. Cyclosporin-A, the active ingredient in NeuroVive’s first product NeuroSTAT®, has for years been used for immunosuppression in organ transplantation.

In contrast to currently commercially available intravenous cyclosporin-A used for immune suppression, NeuroSTAT® does not contain cremophor® or ethanol. Importantly, studies have reported that cremophor® can cause hypersensitivity reactions (anaphylaxis) in treated patients. With NeuroSTAT®, a cremophor®- and ethanol-free product, NeuroVive’s objective is to provide healthcare providers worldwide with a non-allergenic advanced new formulation of cyclosporin-A for neuroprotection in the treatment of moderate to severe neurological damage in patients with traumatic brain injury.

NeuroSTAT® is a designated orphan drug for moderate and severe TBI in Europe and the U.S.

About the European Brain Injury Consortium

Constituted in 1995, the European Brain Injury Consortium (EBIC) is a network of European neurological research and medical units highly experienced in the care of patients with brain injuries. EBIC was founded to promote international, multi-center, interdisciplinary research aimed at improving the outcomes of patients who have suffered head injury or other acute brain damage.

About NeuroVive

NeuroVive Pharmaceutical AB is a Swedish drug development company whose primary mission is to develop drugs that protect nerve cells. In addition to conducting clinical trials of NeuroSTAT® — the first cyclophilin-D-inhibiting mitochondrial protectant — NeuroVive is researching and developing variants of cyclophilin-D-inhibiting cyclosporins and new ways of transporting these drugs across the blood–brain barrier to the central nervous system. NeuroVive’s shares are listed on the Swedish trading platform AktieTorget (www.aktietorget.se). The AktieTorget market is focused on emerging, entrepreneurial businesses through an electronic trading system supplied by the OMX Nordic stock exchange in Stockholm, Sweden.

For further information contact:

Mikael Brönnegård, MD, CEO, NeuroVive Pharmaceutical AB

Telephone: +46 46 288 0110 Cell: +46 70 299 6264

E-mail: mikael.bronnegard@neurovive.com

Web: www.neurovive.com

Mailing address: Biomedical Center BMC D10, SE-221 84 Lund, Sweden