



PRESS RELEASE

NeuroVive Obtains U.S. Orphan Drug Designation for Traumatic Brain Injury

Note: This is an English version of a press release communicated by NeuroVive 2010-12-01

December 6, 2010 – Lund, Sweden. NeuroVive Pharmaceutical AB (NVP) announces that the U.S. FDA Office of Orphan Products Development has granted an Orphan Drug Designation to the company's NeuroSTAT® (cyclosporine) product for the treatment of moderate to severe traumatic brain injury. The Orphan Drug Designation covers both open and closed moderate to severe traumatic brain injury and gives NeuroVive market exclusivity for NeuroSTAT® in the United States for seven years from the date of marketing approval.

CEO Michael Bronnegard comments:

"The U.S. Orphan Drug Designation for NeuroSTAT® was granted for patients with both open and closed traumatic brain injury, which exceeded our expectations. It indicates that there is indeed a significant medical need in this group of patients, where no effective pharmaceutical treatment is yet available to treat acute neurodegenerative injuries. Obtaining Orphan status in the U.S. is an important milestone in our company's efforts to develop an effective drug for acute brain injuries and this designation can facilitate more rapid development and commercialization in the United States."

Orphan Designation

FDA Orphan Drug Designation is intended to support the clinical development of drugs for diseases and conditions that affect fewer than 200,000 people in the United States. Orphan Drug Designation gives market exclusivity for seven years in the U.S. from the date the product receives marketing approval. Orphan Drug Designation also provides access to regulatory support from the FDA throughout the development process. Designation does not imply that the product has demonstrated the efficacy, safety and quality required for drug approval in the U.S. These criteria must be met in the clinical phase of development and receive approval from the FDA before a market authorization for the product is granted.

About NeuroVive

NeuroVive is a Swedish drug development company focused on cyclosporine-based cyclophilin D inhibitors for mitochondrial neuroprotection. The active ingredient in NeuroVive's lead product NeuroSTAT®, cyclosporine (cyclosporin-A), has been repurposed for neuroprotection after years of use in humans for immunosuppression in organ transplantation. NeuroSTAT®, a cremophor®- and ethanol-free intravenous cyclosporine product, is in clinical trials to evaluate its suitability for patients with traumatic brain injury and other acute neurological injuries. NeuroVive shares are listed on the Swedish trading platform AktieTorget (www.aktietorget.se). The AktieTorget market is focused on emerging, entrepreneurial businesses via an electronic trading system supplied by the OMX Nordic stock exchange in Stockholm, Sweden.

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