



NEWS RELEASE

600th heart attack patient recruited into Phase III CicloMulsion® CIRCUS trial

Lund (Sweden) – March 22, 2013, NeuroVive, a leading mitochondrial medicine company, announces that the 600th patient has been recruited to a pivotal Phase III European, multi-center trial (CIRCUS trial) assessing CicloMulsion® (a special formulation of cyclosporine for acute cardiac injuries) for the treatment of heart reperfusion injury following stenting in patients with myocardial infarction.

The CIRCUS trial (does Cyclosporine ImpRove Clinical oUtcome in ST elevation myocardial infarction patients) is assessing CicloMulsion® in a study of nearly 1,000 patients undergoing stenting following acute myocardial infarction to examine its ability to protect cardiac tissue and improve clinical outcome. CicloMulsion® is a Cremophor®-free formulation of the cyclophilin inhibitor, cyclosporine, under clinical development by NeuroVive for the treatment of cardiac reperfusion injury.

In 2008 a 58 patient study published in the New England Journal of Medicine (NEJM, 2008 Jul 31; 359 (5): 473-81) showed cyclosporine, when administered immediately prior to stenting, could reduce reperfusion injury by 40% in patients with myocardial infarction. The CIRCUS trial is designed to confirm these results in a much larger patient group.

The trial is a multicentre, randomized, placebo-controlled, double-blind, investigator-initiated study. Patients receive one single injection of CicloMulsion® (or placebo) prior to reperfusion therapy by stenting. The incidence of the combined endpoint (mortality, hospitalization for heart failure, left ventricular (LV) remodelling) is then assessed one year after treatment to determine whether cyclosporine can improve ST Elevation acute Myocardial Infarction (STEMI) patient clinical outcome. The study also includes a number of secondary outcome measures designed to provide a more detailed insight into CicloMulsion's ability to reduce a patient's level of cardiac injury following stenting.

The trial is being led by trial sponsor Professor Michel Ovize, MD, PhD, of the University Hospital in Lyon (HCL), a leading expert in the field of cardiovascular medicine and it is conducted by a CRO unit within the hospital according to good clinical practice (GCP) guidelines. The study is enrolling patients at centres in France and additional sites in Belgium and Spain and is being funded by a number of European grant and public funding bodies. NeuroVive is supporting the study by providing active drug, placebo and drug logistics.

NeuroVive and HCL have recently agreed terms for the commercial use of the CIRCUS trial data which it expects to report in early 2015. If successful, NeuroVive intends to use these data as part of a planned marketing authorization application with the EMA.

Mikael Bronnegard, CEO of NeuroVive Pharmaceutical said: “The CIRCUS trial is very important for NeuroVive since if it confirms earlier trial results and demonstrates a significant improvement in patient outcome it will reinforce our view that CicloMulsion® is an important new treatment for heart reperfusion injury following stenting. Therefore, the fact that the 600th patient has been recruited to the trial is greatly encouraging. The trial has been designed and conducted to the highest standards and we intend to use the data from this pivotal study for a Marketing Authorization Application in Europe for CicloMulsion®.”

Professor Michel Ovize commented: “Reperfusion injury following stenting is affecting a growing global patient population suffering from cardiovascular disease. This group represents a huge medical need and one for which there are currently no approved pharmaceutical treatment options available. It is therefore critical to develop a drug to protect cardiac tissue following stenting. Cyclosporine has already shown the potential to reduce significantly the level of reperfusion injury and we are looking forward to confirming this important finding in the current CIRCUS study.”

The novel Cremophor®-free formulation for cyclosporine

CicloMulsion® is a special formulation of cyclosporine for use in acute cardiac indications. It has the following advantages:

- (i) Ready-to-use solution. The ready to hang and administer bottles do not require dilution from a concentrate, thus reducing measuring and dosing errors.
- (ii) Formulated with physiological fats and phospholipids that can be readily metabolized by the human body.
- (iii) No risk of Cremophor®-related severe hypersensitivity reactions or anaphylactic reactions.
- (iv) No risk of Cremophor®-related cyto-, nephro- and cardiotoxicity.

About NeuroVive Pharmaceutical AB (publ)

NeuroVive Pharmaceutical AB (www.neurovive.com) a leading mitochondrial medicine company is developing a portfolio of products to treat acute cardiovascular and neurological conditions through mitochondrial protection.

NeuroVive’s products are based on the cyclophilin inhibitor cyclosporine and work by preventing the death of mitochondria in distressed cells and the subsequent cascade of intracellular biochemical events that lead to secondary tissue damage following an acute cardiac or traumatic brain injury.

NeuroVive’s lead product is CicloMulsion®, the first cyclophilin inhibitor for the treatment of reperfusion injuries following stenting. CicloMulsion® is currently in a 1000 patient Phase III clinical trial evaluating its ability to reduce reperfusion injuries in patients with myocardial infarction.

NeuroVive is also developing NeuroSTAT®, a cyclophilin inhibitor, which is soon expected to enter a Phase IIa clinical trial in patients with severe traumatic brain injury. Both indications have huge medical need and for which there are currently no approved pharmaceutical treatment options. Both CicloMulsion® and NeuroSTAT® are special formulations of cyclosporine for use in acute cardiac and brain injury indications.

NeuroVive's pipeline includes novel cyclophilin inhibitors, and drug candidates that act on mitochondria to address energy regulation disorders.

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.

About the Hospices Civils de Lyon

University Hospital of Lyon (HCL) is a public institution and the second-largest university hospital in France, with an annual budget of over 1.3 billion euros. It covers five hospital clusters in the Lyon urban area and a large number of academic research laboratories. HCL employs 20,000 people, including 2,700 physicians with the latest and most advanced technology to improve patient care not only in Lyon but also globally. HCL handles about 530 emergency cases and more than 2,300 outpatient visits daily.

HCL's capabilities include clinical trials (three clinical trial centers) and contract manufacturing for the production of pharmaceuticals and contract research. HCL has one of Europe's best-developed university structures in terms of clinical research and clinical drug trials. Responsibility for clinical research and clinical trial programs rests with the Division of Clinical Research and Innovation (DRCI). HCL has 5,000 hospital beds providing an environment conducive to conducting clinical research. Each year there are approximately 500 clinical research projects within the framework of HCL's business and up to 2009 more than 1000 clinical trials in various specialties had been performed.

Media and investor relations contacts

NeuroVive Pharmaceutical: Mikael Bronnegard

Email: info@neurovive.com

Phone No: +46 (0) 70 299 62 64

Citigate Dewe Rogerson: Nina Enegren / David Dible

Email: nina.enegren@citigatedr.co.uk

Phone No: +44 207 282 1050