



NEWS RELEASE

NeuroVive announces publication of Phase I clinical trial of CicloMulsion® in Clinical Drug Investigation

Lund (Sweden) - December 3, 2012. NeuroVive announces publication of the results of a Phase I clinical trial of lead product CicloMulsion® in the scientific journal Clinical Drug Investigation. The paper highlights that the intravenous cyclosporine formulation CicloMulsion® demonstrates bioequivalence and improved tolerability when compared with Sandimmune® Injection.

The mitochondrial medicine company NeuroVive Pharmaceutical today announces publication of the Phase I clinical study comparing CicloMulsion®, the Cremophor®-free intravenous cyclosporine formula (also known under the product name NeuroSTAT®), to Sandimmune® Injection. The results of the trial that were first announced by NeuroVive in 2010 have now been published in the peer-reviewed journal Clinical Drug Investigation.

The paper, titled “Bioequivalence and Tolerability Assessment of a Novel Intravenous Cyclosporine Lipid Emulsion Compared to Branded Cyclosporine in Cremophor® EL”, highlights that primary and secondary endpoints of the trial were met demonstrating that CicloMulsion® is bioequivalent to Sandimmune® Injection and is safe and well tolerated. The full paper can be downloaded on the publisher website by accessing the following link:

<http://link.springer.com/article/10.1007/s40261-012-0029-x>

CicloMulsion®, a Cremophor®-free formulation of the cyclophilin inhibitor cyclosporine, is in clinical development by NeuroVive for the treatment of cardiac reperfusion injury. Under the name NeuroSTAT® the formulation is also being developed for the treatment of traumatic brain injury. The active ingredient cyclosporine acts by preventing the death of mitochondria in damaged cells and the following cascade of intracellular biochemical events that lead to secondary tissue damage. By protecting a cell’s mitochondria, NeuroVive’s products ensure that energy production is preserved and a damaged cell’s normal regenerative mechanisms can act to repair and maintain the cell.

The paper reports the Phase I bioequivalence, safety and tolerability study in which fifty-two healthy volunteers were administered single intravenous doses of each of the two cyclosporine formulations in a randomized single-blind cross-over washout design. All pharmacokinetic variables (including the FDA and EMA required parameters) were within the range required to show bioequivalence.

The proportion of adverse events was significantly higher when subjects were treated with Sandimmune® compared to CicloMulsion®. Two serious adverse events requiring qualified medical treatment were recorded in subjects receiving Sandimmune®. As a result, the study protocol was changed and all subjects received protective pre-medication. CicloMulsion® was safe and well tolerated.

Eskil Elmer, CSO of NeuroVive Pharmaceutical and senior author of the publication, said:

“The publication of the results of the Phase I trial with our novel intravenous formulation for cyclosporine in this quality peer-reviewed journal is an important step of the go-to-market strategy for our products for treatment of traumatic brain injury and cardiac reperfusion injury. The trial clearly shows that our formulation is bioequivalent to Sandimmune®, yet free from Sandimmune®’s risk of causing anaphylactic and hypersensitivity reactions, thus providing a firm foundation on which to bring CicloMulsion® and NeuroSTAT® to cardiac and brain injured patients. NeuroSTAT® is

expected to soon enter a Phase II clinical trial in patients with severe traumatic brain injury and CicloMulsion® is currently in a 1000-patient Phase III trial for cardiac reperfusion injury.”

In addition to the full publication, further information on the Phase I clinical study can be found at ClinicalTrials.gov by accessing the following link: <http://clinicaltrials.gov/ct2/show/NCT01692834>

The novel Cremophor®-free formulation for cyclosporine

CicloMulsion® and NeuroSTAT® are special formulations of cyclosporine for use in acute cardiac and brain injury indications. They have 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® EL-related severe hypersensitivity reactions or anaphylactic reactions.
- (iv) No risk of Cremophor® EL-related cyto-, nephro- and cardiotoxicity.

Cremophor® EL

Cremophor® EL is a detergent-like agent used to keep lipophilic drugs in solution. Cremophor® EL is implicated in hypersensitivity and anaphylactic reactions. For most Cremophor®-containing intravenous drugs, like Taxol®, corticosteroids are a required premedication to reduce the risk of these reactions. Cremophor® is not usually present in newer drug formulations for this safety reason, including the propofol intravenous anesthetic Diprivan® and the paclitaxel intravenous chemotherapeutic agent Abraxane®. Sandimmune® Injection contains Cremophor®. CicloMulsion® is Cremophor®-free.

About NeuroVive Pharmaceutical AB

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

NeuroVive’s products for neuro- and cardioprotection are based on the cyclophilin inhibitor cyclosporine that prevents the death of mitochondria in distressed cells and the subsequent cascade of intracellular biochemical events, thereby protecting cellular energy supply and reducing secondary tissue damage.

NeuroVive’s lead product is CicloMulsion®, the first cyclophilin inhibitor for the treatment of reperfusion injuries following stenting of coronary arteries after myocardial infarction. CicloMulsion® is currently in a 1000 patient Phase III clinical trial evaluating its ability to reduce reperfusion injuries in patients with myocardial infarction. The study is entitled “Cyclosporine and Prognosis in Acute Myocardial Infarction (MI) Patients (CIRCUS)”. Information on the Phase III clinical study can be found at ClinicalTrials.gov by accessing the following link: <http://clinicaltrials.gov/ct2/show/NCT01502774>

NeuroVive is also developing the cyclophilin inhibitor NeuroSTAT® which is soon expected to enter a Phase II clinical trial in patients with severe traumatic brain injury. Both cardiac reperfusion injury and traumatic brain injury are indications with huge unmet medical need and no approved pharmaceutical treatment options.

NeuroVive’s pipeline includes a cyclophilin D inhibitor for stroke and drug candidates aimed at mitochondrial energy deficiency.

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.

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