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NeuroVive reports favourable safety evaluation in Phase II acute kidney injury study

Lund, Sweden, 19 November 2015 – NeuroVive Pharmaceutical AB (publ), the mitochondrial medicine company, announces that the independent safety committee has endorsed the continuation of the on-going Phase II CiPRICS (Ciclosporin to Protect Renal function In Cardiac Surgery) study following the enrolment of the first 50 patients in the study.

The assessment is conducted in order to evaluate the treatment's safety profile. On the basis of satisfactory safety findings, the study will continue as planned with the goal to enrol 150 patients and complete the study in the second half of 2016. The CiPRICS study has enrolled about 60 patients to date and is progressing as planned.

The CiPRICS study is an investigator led Phase II Double Blind Randomized Placebo Controlled Study evaluating ciclosporin (CicloMulsion®) for the prevention of acute kidney injury (AKI) in patients undergoing major surgery. The study is a proof of concept study for AKI and further studies will be required in order to advance the NeuroVive clinical development program in this area. Henrik Bjursten, MD, PhD is the Principal Investigator of the study, which is being conducted at the Department of Cardiothoracic Surgery at Skåne University Hospital.

"This independent assessment shows that there seems to be no safety issues with ciclosporin (CicloMulsion®) in this patient population and allows us to continue our investigation in acute kidney injury which is of high interest to our team in Lund," Dr. Henrik Bjursten commented.

"This is an important milestone for our clinical development programme in acute kidney injury and provides NeuroVive with confidence to further progress our research in this core therapy area. We will continue to work closely with the study investigators to move forward from here, complete the study and have the results available in the second half of 2016," Jan Nilsson, NeuroVive interim Chief Executive Officer commented.

Acute kidney injury (AKI) may occur after major surgeries, such as coronary artery bypass surgery (CABG), which is performed annually in over 400,000 people worldwide. There are currently no approved pharmacological AKI treatment options available and patients with AKI during CABG surgery risk developing end stage renal disease, which is a serious and costly consequence requiring dialysis in a number of cases. There is growing interest both scientifically and commercially in AKI based on the need to provide new treatment options for these patients. Earlier this year, Pfizer acquired a minority interest in A-M Pharma for their AKI investigational compound, which highlights the growing interest in this therapeutic area.

About NeuroVive

NeuroVive Pharmaceutical AB (publ) is a leading mitochondrial medicine company committed to the discovery and development of highly targeted candidates that preserve mitochondrial integrity and function in areas of therapeutic need. NeuroVive's business approach is driven by value-adding

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partnerships with leading mitochondrial research institutions and commercial partners across the globe.

NeuroVive's portfolio consists of two projects in acute kidney injury (AKI) and traumatic brain injury (TBI) with candidates in clinical and preclinical development and two drug discovery platforms. The NeuroSTAT® product is currently being evaluated in a Phase II study in traumatic brain injury. CicloMulsion® is being evaluated in an on-going Phase II study, CiPRICS, in acute kidney injury during major surgery. NeuroVive's shares are listed on NASDAQ OMX, Stockholm, Sweden.

More information about the study

The CiPRICS study (Ciclosporin to Protect Renal function In Cardiac Surgery) is a double-blind, randomized and placebo-controlled clinical Phase II study including a total of 150 patients. The patients are being treated with CicloMulsion® or placebo in connection with coronary artery bypass surgery (CABG) at the Department of Cardiothoracic Surgery at Skåne University Hospital in Lund, Sweden. The study is investigator-initiated and is conducted by Skåne University Hospital with support from NeuroVive, which is providing the investigational product, CicloMulsion®. In addition to the predefined safety analyses, the safety profile of the treatment is evaluated continuously. More information about the study has been published in the public database ClinicalTrials.gov at <https://clinicaltrials.gov/ct2/show/NCT02397213>

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It is also possible to arrange an interview with NeuroVive's interim CEO Jan Nilsson at the above contacts.

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