## **PRESS RELEASE**

NeuroVive Pharmaceutical AB (publ) 556595-6538



# NeuroVive discontinues development of CicloMulsion for acute kidney injury

**Lund, Sweden, October 13, 2016 - NeuroVive Pharmaceutical AB (Nasdaq Stockholm: NVP, OTCQX: NEVPF),** the mitochondrial medicine company, today announced results from the exploratory clinical phase II study CiPRICS. The results clearly show that patients treated with CicloMulsion prior to open heart surgery experience no benefit compared to placebo in the prevention of acute kidney injury (AKI). As a result, NeuroVive will discontinue the development of CicloMulsion for AKI.

The exploratory CiPRICS study, aimed at preventing AKI in patients undergoing open heart surgery, did not reach the primary objective. In contrast, patients in the active dose group showed a transient, but statistically significant increase in the biomarkers P-cystatin C and P-creatinine compared to placebo. No unexpected tolerability issues were observed and the overall frequencies of serious adverse events were comparable to those observed in the placebo group.

"Since the overall goal for this study was to offer a preventive treatment to patients at risk of developing AKI, the outcome of the study was a disappointment. However, the CiPRICS study has given us very important information about ciclosporin treatment in this patient population. Also, we have appreciated the fruitful and close collaboration with the NeuroVive clinical team", says Sponsor-Investigator, Associate Professor Henrik Bjursten M.D. Ph.D., Department of Cardiothoracic Surgery, Anesthesia and Intensive Care at Skåne University Hospital in Lund, Sweden.

Given the current findings, NeuroVive has decided to discontinue the development of CicloMulsion in AKI and redirect resources to its other development assets. NeuroVive continues to progress its opportunities within mitochondrial medicine, an area with high unmet medical needs. The ciclosporin (NeuroSTAT) development program in traumatic brain injury (TBI) will proceed. NeuroVive will continue development of its unique non-Ciclosporin based cyclophilin inhibitors for organ protection and other unrelated indications. In addition to these high-value possibilities, NeuroVive has several other promising early projects with different, novel modes of action within the area of mitochondrial medicine.

"The CiPRICS study has been excellently conducted by the team, led by Associate Professor Bjursten at Skåne University Hospital, with clear results. Moreover, it has verified the effectiveness of the network partnership model for NeuroVive's early clinical development", says NeuroVive's CEO Erik Kinnman. "We will continue to develop and build our portfolio, and I see several potential upcoming milestone events in our strong and diversified mitochondrial medicine portfolio."

A web cast for presentation of the study results will be held at 3:00 p.m. today. To listen to the presentation please visit <a href="https://wonderland.videosync.fi/2016-10-13-neurovive-press-conference.">https://wonderland.videosync.fi/2016-10-13-neurovive-press-conference.</a> To callin please use one of the following numbers: Sweden: +46856642690 UK: +442030089815 US: +18558315946.

Dr. Bjursten will this afternoon give an oral presentation with the title *Ciclosporin to Protect Renal Function In Cardiac Surgery (CiPRICS). A Double Blind, Randomised, Placebo Controlled, Proof of Concept Study* at the Swedish Thorax meeting in Malmö. For further information about the program, please visit the conference web site:

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### http://www.malmokongressbyra.se/svenska thoraxmotet/program.

#### **About CiPRICS**

The CiPRICS study (Ciclosporin to Protect Renal Function In Cardiac Surgery) was a double-blind, randomized and placebo-controlled exploratory phase II study that investigated NeuroVive's candidate drug CicloMulsion in the prevention of acute kidney injury (AKI) in open heart surgery. The primary endpoint was relative changes in P-cystatin C between the treatment groups three days after surgery. Secondary endpoints included evaluation of P-creatinine and other biomarkers of kidney, heart and brain injury. The study encompassed 155 patients who were treated with CicloMulsion or placebo prior to coronary artery bypass surgery (CABG) at the Department of Cardiothoracic Surgery, Anesthesia and Intensive Care at Skåne University Hospital in Lund, Sweden. The study was investigator-initiated and performed by Skåne University Hospital with support from NeuroVive. More information about the study is published in the public database <a href="https://www.clinicalTrials.gov">www.clinicalTrials.gov</a>.

#### **About NeuroVive**

NeuroVive Pharmaceutical AB (Nasdaq Stockholm: NVP, OTCQX: NEVPF), is a pioneer in mitochondrial medicine and a company committed to the discovery and development of highly targeted candidates that preserve mitochondrial integrity and function in areas of significant therapeutic need. NeuroVive's business approach is driven by value-adding partnerships with mitochondrial research institutions and commercial partners across the globe. NeuroVive is listed on Nasdaq Stockholm, Sweden, Small Cap, under the ticker symbol NVP. The share is also traded on the OTC Markets Group Inc. market in the US. NeuroVive Pharmaceutical (OTC: NEVPF) trades on the OTCQX Best Market.

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