

NEWS RELEASE

NeuroVive Pharmaceutical AB (publ)
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1 June, 2015



NeuroVive reports topline results of phase III CIRCUS study in acute myocardial infarction

NeuroVive Pharmaceutical AB (publ), the mitochondrial medicine company, reports that the phase III CIRCUS study of CicloMulsion® in patients with a specific type of heart attack known as ST-segment elevation acute myocardial infarction (STEMI) did not meet its primary clinical endpoint in a topline analysis.

The topline analysis of the study data provides information on whether the primary endpoint has been met or not. This result does not contain specific data concerning the level of significance for either the composite endpoint or each individual element of the composite endpoint. These will be revealed in the subsequent detailed analysis. It is anticipated that the full results of the 12-month data from the CIRCUS study will be made available in the third quarter. Today's topline result is expected to delay the commercialization of CicloMulsion®.

"While the primary endpoint of the CIRCUS study has not been met, analysis of the full 12-month data set will provide us with more information in regard to which patients may have benefited from treatment with CicloMulsion®. These results will help define next steps in the development and commercialization of CicloMulsion®. The CIRCUS study is an independent, investigator-led study and we will continue to collaborate with the lead investigator to further evaluate the full 12-month study results as they become available," commented NeuroVive's CEO Mikael Brönnegård.

"We are confident in the NeuroVive R&D pipeline and the potential of cyclophilin inhibitors including CicloMulsion®. CicloMulsion® is one of several products and projects in clinical and preclinical stages including the ongoing phase II CiPRICS and CHIC studies. Our continuing clinical program coupled with a strong research and development pipeline will support NeuroVive's future growth," he added.

The primary endpoint is a composite of three separate outcomes: mortality, hospitalization for heart failure and left-ventricular (LV) remodeling at 12 months post acute myocardial infarction. The primary objective of the study was to determine whether CicloMulsion® can improve STEMI patient clinical outcomes 12 months after administration. CicloMulsion® or placebo was administered directly prior to percutaneous coronary intervention (PCI), a common procedure to reopen the coronary artery allowing the return of blood flow to the heart. The study will continue for a further two years to investigate longer term outcomes. CicloMulsion® is an investigational product and has not been approved by regulatory agencies for the treatment of any medical condition.

The impact of the CIRCUS results on the future development of CicloMulsion® will be communicated in the second half of 2015.

About ST-segment elevation myocardial infarction (STEMI)

Acute myocardial infarction (AMI), commonly known as heart attack, is caused by blockage of a coronary artery obstructing blood flow to the tissue of the heart, which results in cell damage or death (infarct) leading to reduced heart function, heart failure and possible death. STEMI is a diagnostic classification of more severe myocardial infarction in which the damage to the cardiac muscle, caused by complete coronary artery blockage, is first detected by electrocardiography (ECG).

About the CIRCUS study

The CIRCUS study (does Cyclosporine ImpRove Clinical oUtcome in ST elevation myocardial infarction patients) is an ongoing phase III study assessing CicloMulsion® in 975 patients undergoing PCI following STEMI to assess its ability to protect cardiac tissue and improve clinical outcomes.

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The study is a multicentre, randomized, placebo-controlled, double-blind, investigator-initiated study. Patients received one intravenous dose of CicloMulsion® (or placebo) prior to reperfusion therapy by PCI. The incidence of the combined endpoint (mortality, hospitalization for heart failure, LV remodeling) will be assessed at 12 months after treatment to determine whether CicloMulsion® can improve the clinical outcome in STEMI patients. 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 PCI. There will also be further analyses at 36 months after treatment to discover longer term effects of CicloMulsion®.

The trial is being led by Professor Michel Ovize, MD, PhD, of Hospices Civils de Lyon (HCL), a leading expert in the field of cardiovascular medicine and it is conducted by a clinical research organization (CRO) unit according to good clinical practice (GCP) guidelines. The study has enrolled patients at centres in France, Belgium and Spain. The CIRCUS trial is an investigator-initiated trial that is supported by a national PHRC program funded by the French Ministry of Health (PHRC National 2010). Furthermore, it is supported by grants from NeuroVive Pharmaceutical AB, Lund, Sweden, that also provides the study treatment CicloMulsion® and matching placebo. Further details of this study can be obtained at:

<https://www.clinicaltrials.gov/ct2/show/NCT01502774?term=CIRCUS&rank=1>

About CicloMulsion®

NeuroVive's drug candidate CicloMulsion®, a cremophor-free lipid emulsion formulation of cyclosporine, is the first cyclophilin inhibitor in development for the treatment of reperfusion injury. It is designed to prevent mitochondria dysfunction in damaged cells and limit the numerous biochemical processes that lead to secondary tissue damage. By protecting the mitochondria, CicloMulsion® may safeguard continued energy production and ensure that the normal healing process is able to carry out repairs and maintain cell functionality. CicloMulsion®'s potential for treatment in connection with STEMI is currently being evaluated in a clinical phase III study. CicloMulsion® is also being evaluated in a phase II study for the prevention of renal injury during major heart surgery with Skåne University Hospital in Lund, Sweden. CicloMulsion® is an investigational product and has not been approved by regulatory agencies for the treatment of any medical condition.

About NeuroVive

NeuroVive Pharmaceutical AB (publ), the mitochondrial medicine company, is developing a portfolio of products to treat acute conditions through mitochondrial protection. NeuroVive's product CicloMulsion® is being evaluated in an ongoing phase III study, CIRCUS, in myocardial infarction (STEMI) and a phase II study, CIPRICS, in acute kidney injury. The NeuroSTAT® product is currently being evaluated in a phase II study in traumatic brain injury. NeuroVive's research programs also include development of drug substances against brain injury in stroke patients, and for cellular protection and energy regulation in mitochondrial disease. NeuroVive's shares are listed on NASDAQ OMX, Stockholm, Sweden.

Disclaimer

This release may contain forward-looking statements that can be identified by words such as "recommends," "indicating," "risk," "recommended," "believe," "could," "commitment," "will," "implications," "supports," "thought," "designed," "growing," "continues," or similar terms, or by express or implied discussions regarding potential marketing approvals for CicloMulsion®, or regarding potential future revenues from CicloMulsion®. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that CicloMulsion® will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that CicloMulsion® will be commercially successful in the future. In particular, management's expectations regarding CicloMulsion® could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial

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results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected manufacturing issues, and other risks and factors.

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

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