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OrbusNeich Announces the Last Patient Enrollment in Physician-Initiated Study to Evaluate the Potential for Shorter Dual Antiplatelet Therapy in ACS Patients

A randomized, multicenter study evaluating patients with acute coronary syndrome who received the COMBO™ Dual Therapy Stent

Hong Kong [3 May 2016] OrbusNeich announced the completed enrollment in the REDUCE trial – a physician-initiated, prospective, multicenter, randomized study, designed to evaluate the potential for shorter-term dual antiplatelet therapy (DAPT) in acute coronary syndrome (ACS) [https://clinicaltrials.gov/ct2/results?term=NCT02118870]. All patients will receive the COMBO Dual Therapy Stent with an abluminal sirolimus drug elution and endothelial progenitor cell (EPC) technology that actively captures EPCs and accelerates formation of healthy endothelial coverage.

“The safety and efficacy of the COMBO stent has already been proven in previous trials, but the benefits of accelerated endothelialization can set this stent apart by enabling a reduced DAPT regimen”, said Prof. Harry Suryapranata, principal study investigator from Radboud University Medical Center, Nijmegen, The Netherlands.

“This offers a significant degree of freedom in the treatment of ACS patients. Early discontinuation of DAPT reduces the inherent bleeding risk and the healing characteristics of the COMBO offers great potential in enabling this without compromising overall safety” added co-principal study investigator, Prof. Giuseppe De Luca from the Eastern Piedmont University Hospital, Novara, Italy. “The REDUCE trial is the first study to evaluate the reduction of DAPT following treatment with the COMBO Stent and may provide us with evidence to support the safety of three months DAPT in ACS patients.”

The REDUCE trial began in June 2014 and has now completed enrollment of 1,500 patients in 36 centers in Asia and Europe. This trial evaluates the composite endpoint of all-cause mortality, any myocardial infarction, target vessel revascularization, stroke or major bleeding in patients receiving either

three or 12 months of DAPT after a period of 1 year. Patients have been randomized in a 1:1 fashion. The REDUCE study is managed by Diagram Research Organization, The Netherlands.

About the COMBO Dual Therapy Stent
COMBO is the world's first and only dual therapy stent designed to repair vessel injury and regenerate endothelium, fostering natural, true vessel healing. It does this by accelerating endothelial coverage and controlling neo-intimal proliferation. This is done through a combination of the proven EPC capture technology and a sirolimus drug elution, delivered from a bioresorbable polymer that is completely degraded within 90 days.

OrbusNeich's patented endothelial progenitor cell (EPC) capture technology promotes the accelerated natural healing of the vessel wall after the implantation of blood-contact devices such as stents. The technology consists of an antibody surface coating that captures EPCs circulating in the blood to the device to form an endothelial layer that provides protection against thrombosis and modulates restenosis.

About OrbusNeich – Pioneers in life-changing technologies
OrbusNeich is a global pioneer in the provision of life-changing vascular solutions and offers an extensive portfolio of products that set industry benchmarks in vascular intervention. Current products are the world's first dual therapy stent, the COMBO Dual Therapy Stent, and the world's first pro-healing stent, the Genous™ Stent. Other products include stents and balloons marketed under the names of Azule™, Scoreflex™, Sapphire™ II, Sapphire™ II Pro and Sapphire™ II NC. OrbusNeich is headquartered in Hong Kong and has operations in Shenzhen, China; Fort Lauderdale, Florida, USA.; Hoevelaken, The Netherlands; and Tokyo, Japan. OrbusNeich supplies medical devices to interventional cardiologists in more than 60 countries. For more information, visit www.OrbusNeich.com

About Diagram
Diagram is a global full service Contract Research Organization (CRO) with two Site Management Organizations (SMOs). Diagram is able to support with the development, organization and execution of clinical scientific research. Diagram was founded in 1996 in the Netherlands. In the past years, Diagram has acquired considerable expertise in supporting cardiovascular research. The quality management of Diagram (NEN-EN-ISO 9001:2008 certified); strong ICT, data management and statistics department; own SMO's, and international focus makes Diagram different from other CRO's. Please visit http://www.diagram-zwolle.nl/