OrbusNeich
Pioneers in life-changing technologies

Global Media Contact:
Christine Lydon
+44-20-8618-2889
christine.lydon@fhflondon.co.uk

Deborah Woods
+44-7787-575-251
dwoods@orbusneich.com

OrbusNeich's COMBO™ Dual Therapy Stent Demonstrates Non-inferiority vs the Market Leading XIENCE™ Everolimus Eluting Stent

One-year results from the pivotal HARMONEE trial reported at TCT 2017

Denver, USA, October 30, 2017 – New results from the HARMONEE Japan/US Registration Trial, reported by OrbusNeich today in the First Report Investigations session at the 29th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, demonstrate that the COMBO™ Dual Therapy Stent (DTS) compares favorably to the market leading option for treating patients with significant ischemic heart disease.

The Japan-United States of America Harmonized Assessment by Randomized Multicenter Study of OrbusNEich's Combo StEnt (HARMONEE) is a pivotal (Shonin, Japan) registration study being conducted to demonstrate the effectiveness of the combined endothelial progenitor cell capture and drug-eluting stent (COMBO) compared to the Abbott Vascular Xience stent in patients with ischemic coronary disease and non-ST-elevation acute coronary syndrome. The results showed that the overall incidence of the primary endpoint target vessel failure (TVF) was lower than the original estimated 9.0%, with 7.0% in the COMBO group vs 4.2% in the Xience group at 12 months, thereby meeting the non-inferiority requirement (P = 0.020).[1]

"Achieving non-inferiority in TVF compared to the best-in-class current DES, with the addition of superior surrogate measures of site healing by COMBO in this randomized study, represents the opening of an exciting new chapter in percutaneous coronary intervention device design targeting enhanced safety and effectiveness for patients with coronary artery disease," said Principal Investigator Mitchell Krucoff, MD, PhD, Professor of Cardiology, Duke University Medical Center and Duke Clinical Research Institute, Durham, NC, USA.

Kaplan-Meier curves revealed that target vessel revascularization (TVR) events driven by the 1-year protocol re-catheterization were notable in both stent groups, despite the use of fractional flow reserve (FFR) to mitigate such event 'spikes'. The TVF odds ratio of COMBO versus imputed bare-metal stent (BMS) was 0.673 and did not meet the pre-specified assay sensitivity, but the comparison was underpowered due to the low TVF rates (4.2% vs predicted 9%). COMBO was superior to imputed BMS with respect to angiographic in stent (P<0.001) and in segment late loss (P=0.003) at 12 months.

An independent quantitative coronary arteriography core laboratory reported in stent late loss at 1 year of Combo vs Xience of 0.293 mm vs 0.219 mm and in segment late loss of 0.229 mm vs 0.220 mm respectively. Additionally, the angiographic in stent restenosis of Combo vs Xience was 1.3% vs 2.6% and in segment restenosis was 2.5% vs 3.9%.

Optical Coherence Tomography (OCT) at 12 months revealed significantly better healthy tissue strut coverage (thickness >40 micron in patients with normal FFR) with COMBO vs Xience (91.56% vs 74.82%; P<0.001). Also, the qualitative appraisal of the neointima showed more homogeneous tissue with COMBO vs Xience (81.2% vs 68.8%). “OCT observations suggest an active mechanistic role of EPC technology including superior healthy tissue strut coverage with COMBO vs the Everolimus Eluting Stent, and more qualitatively homogeneous neointimal tissue with COMBO,” said Mitchell Krucoff.

The results from HARMONEE build further compelling evidence for COMBO and help to support OrbusNeich’s planned application for approval in Japan and to meet the feasibility trial requirements in the US.

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 through a combination of the proven endothelial progenitor cell (EPC) capture technology and a sirolimus drug elution, delivered from a bioresorbable polymer that is completely degraded within 90 days. OrbusNeich's patented 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 attracts EPCs circulating in the blood to the device to form an endothelial layer that provides protection against thrombosis and modulates restenosis.

About the HARMONEE Study
The HARMONEE study [NCT02073565] was conducted in 50 hospitals in Japan and the USA, enrolling a total of 572 patients, who were randomized to receive a COMBO stent or a Xience stent in a 1:1 fashion. The protocol defined primary clinical endpoint of the HARMONEE study was target vessel failure (TVF), a composite of cardiac mortality, myocardial infarction, or ischemic target vessel revascularization within 1 year days post index treatment. Fractional flow reserve (FFR) was used as an objective quantitative indicator for ischemia. OCT assessments were performed after 6 and 12 months in subsets of patients in order to provide mechanistic insights into the healing patterns in both groups, with attention to factors likely to be affected by the EPC capture technology. All patients were followed up at 12 months with quantitative coronary angiography (QCA), including FFR.

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 stents, the COMBO Plus and COMBO Dual Therapy Stents, together with stents and balloons marketed under the names of Azule™, Scoreflex™, Sapphire™ II, Sapphire™ II PRO and Sapphire™ II NC, as well as products to treat peripheral artery disease: the Jade™ and Scoreflex™ PTA balloons. 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 physicians in more than 60 countries. For more information, visit www.OrbusNeich.com

Reference
Krucoff M, Saito S. HARMONEE: A Randomized Trial of a Bioabsorbable Polymer-Based DES with a Luminal CD34+ Antibody Coating vs a Durable Polymer-Based DES in Patients with Coronary Artery Disease. Oral presentation at the 29th annual Transcatheter Cardiovascular Therapeutics scientific symposium, October 30, 2017.

###