SAN FRANCISCO, Oct. 29, 2013 /PRNewswire/ -- OrbusNeich today announced that new clinical data presented at TCT 2013 show durable outcomes as well as excellent early healing and optimal neointimal suppression out to 24 months following placement of the COMBO Dual Therapy Stent. These results from the EGO-COMBO Study were presented by Stephen W.L. Lee , M.D., of the Queen Mary Hospital, University of Hong Kong , China, at the annual interventional cardiology conference in San Francisco .

The study was the first of its kind to assess the healing profile of a drug eluting stent by longitudinal sequential optical coherence tomography (OCT) and uniquely showed an improvement in outcomes (neointimal regression) between nine and 24 months in terms of neointimal volume (NIV), neointimal thickness (NIT) and plaque volume. Between nine and 24 month OCT follow-up, patients exhibited an 11.3 percent decrease in NIV, from 35.5 mm^3 [30.7-40.3] to 31.5 mm^3 [26.9-36.2] ($p<0.001$); a 4.5 percent decrease in NIT, from 0.156 mm [0.143-0.168] to 0.149 [0.136-0.161] ($p=0.19$); and a 9.7 percent decrease in in-stent percentage neointimal volume, from 17.5 percent [16.0-19.0] to 15.8 percent [14.5-17.1] ($p=0.002$), for the COMBO Dual Therapy Stent. No further stent thrombosis (ST), neoatherosclerosis or clinically driven target lesion revascularization (TLR) were observed.

"We previously reported nine-month results from EGO-COMBO that established the impressive early healing profile of the COMBO Dual Therapy Stent," said Prof. Lee. "These 24 month results now demonstrate the COMBO Dual Therapy Stent's excellent durability over the long-term with a trend of neointima regression observed by OCT. This is the first time ever for a DES reported in the market."

In the study, 61 patients received 88 COMBO Stents with a mean diameter of 3.06 +/- 0.39 mm and a mean length of 23.9 +/- 7.62 mm. OCT was performed at baseline, at early follow-up (before five months) and at nine months in all patients. The clinical follow-up was carried out to 12 months. Per the extension study protocol, 59 patients were evaluated clinically at 24 months,

and, of those, 41 agreed to have a restudy by OCT. All patients received dual antiplatelet therapy (DAPT) for nine months.

The EGO-COMBO Study was designed to assess the healing profile of the COMBO Stent. The primary endpoint of EGO-COMBO was the healing profile (degree of stent strut coverage) at early follow-up and at nine months as determined by OCT. The co-primary endpoints of the EGO-COMBO angiographic extension study were OCT findings on neointimal growth (NIT, NIV and in-stent percentage plaque volume) at 24 months. More information on the study can be found at ClinicalTrials.gov .

The clinical event adjudications, quantitative coronary angiography (QCA) and OCT analyses were performed by the Cardiovascular Research Foundation (CRF) Core Lab in New York.

About the COMBO Dual Therapy Stent

The COMBO Dual Therapy Stent is the first dual therapy stent to both accelerate endothelial coverage and control neo-intimal proliferation through the combination of the proven pro-healing technology with an abluminal sirolimus drug elution delivered from a biodegradable polymer that achieves full and complete dissipation by 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 captures EPCs circulating in the blood to the device to form an endothelial layer that provides protection against thrombosis and modulates restenosis.

About OrbusNeich

OrbusNeich is a global company that designs, develops, manufactures and markets innovative medical devices for the treatment of vascular diseases. 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™, R stent, Scoreflex™, Sapphire™, Sapphire II and Sapphire NC. OrbusNeich is headquartered in Hong Kong and has operations in Shenzhen, China; Fort Lauderdale, Fla.; 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.

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