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REMEDEE Study Meets Primary Endpoint: OrbusNeich's Combo™ Dual Therapy Stent Is Non-Inferior to DES

Results Presented in Late Breaking Clinical Trial Session at TCT 2011

HONG KONG, Nov. 14, 2011 – OrbusNeich today announced that results from the REMEDEE study (**R**andomized **E**valuation of an ablu**M**inal sirolimus coat**ED** bio-**E**ngineered st**E**nt) confirmed that the Combo Dual Therapy Stent is non-inferior to the TAXUS® Liberté® paclitaxel-eluting stent, with respect to in-stent late lumen loss at nine-month angiographic follow-up. The results were presented by Michael Haude, M.D., director of Medical Clinic I at the Lukaskrankenhaus in Neuss, Germany, last week during the Late Breaking Clinical Trials and First Report Investigations Session at Transcatheter Cardiovascular Therapeutics (TCT) 2011 in San Francisco.

The Combo Stent, the world's first dual therapy stent (DTS), combines an abluminal biodegradable sirolimus elution for the regulation of hyperplasia with Genous™,

OrbusNeich's proven endothelial progenitor cell (EPC) capture technology, to accelerate re-endothelialization. The study's primary objective was to demonstrate the safety and effectiveness of the Combo Stent compared to the TAXUS Liberté paclitaxel-eluting stent in patients with symptomatic, ischemic heart disease due to a stenotic lesion located in a native coronary artery. The study's primary endpoint was non-inferiority based on in-stent late lumen loss at nine months.

At nine-month angiographic follow-up, the in-stent late lumen loss for the Combo Dual Therapy Stent was 0.39 +/- 0.45 mm compared to 0.44 +/- 0.56 mm for the TAXUS drug eluting stent (DES).

"This first clinical experience with the Combo Dual Therapy Stent confirms that Combo achieves an antiproliferative effect and safety profile similar to that of current DES," said Prof. Haude. "However, the real differentiating factor for Combo is the Genous pro-healing technology. Using intravascular ultrasound (IVUS) and optical coherence tomography (OCT) imaging, we saw superb homogenous coverage of the Combo stent struts at nine months, compared to less impressive coverage with TAXUS. By harnessing the additive effect of EPC capture to accelerate vessel healing, Combo may potentially enable a significant reduction in the duration of dual antiplatelet therapy (DAPT) in specific cases. These results provide compelling justification for further clinical study of the Combo Stent."

The study's secondary endpoints included clinically driven target lesion revascularization (TLR), binary restenosis, major adverse cardiac events (MACE) and stent thrombosis (ST) rates, as well as all-cause and cardiac mortality, myocardial infarction (MI) and target lesion failure (TLF) at 30 days, nine months and one through five years. Though the study was not powered to establish statistical significance for the secondary endpoints, the following trends in favor of Combo were observed at nine months: for patients treated with Combo, the rate of clinically driven TLR was 45% lower than in the TAXUS group, the binary restenosis rate was 43% lower than the TAXUS group, and the MACE rate was 21% lower than the TAXUS group. No stent thrombosis (ST) was observed in either cohort.

“With these exciting results in hand, we have filed our CE mark application for Combo,” said Al Novak, OrbusNeich’s chairman of the board, president and CEO. “Combo’s dual therapy approach was conceived to address the major issue that still faces drug eluting stents, specifically the risk of stent thrombosis (ST) associated with delayed or absent healing. These results place Combo in the running to become the better drug eluting stent – a drug eluting stent that heals.”

REMEDEE is an ongoing first-in-man, prospective, randomized, multicenter study that includes 183 patients with symptomatic, ischemic heart disease due to a stenotic lesion located in a native coronary artery at sites in Asia, Australia, Europe and South America. Patients underwent percutaneous coronary intervention (PCI) for the treatment of single *de novo* native coronary lesions ranging in diameter from greater than or equal to 2.5 mm and less than or equal to 3.5 mm and less than or equal to 20 mm in length.

The average reference vessel diameter (RVD) was 2.77 mm for the Combo group and 2.85 mm for the TAXUS group, and the average stent length was 13.7 mm for Combo and 14.6 mm for TAXUS. Of the lesions treated, 66.2% were type B2/C lesions in the Combo group, and 61.0% were type B2/C in the TAXUS group. For patients treated with Combo, 33.1% had diabetes mellitus, compared to 37.3% for TAXUS.

“We are now focused on establishing the healing profile of Combo versus the latest generation of drug eluting stents,” said Stephen M. Rowland, Ph.D., vice president of research & development, at OrbusNeich. “Particularly, we expect that data from our randomized REMEDEE OCT study will establish Combo’s superiority in the speed and quality of vessel healing, as indicated by stent strut coverage, versus everolimus eluting stents. In addition, we are in the process of designing a pivotal trial to be used for simultaneous regulatory approval in the U.S. and Japan, which we plan to initiate as early as the end of next year. Additionally, the company has begun the submission process for the People’s Republic of China, and we look forward to bringing the Combo Dual Therapy Stent to interventional cardiologists and their patients worldwide.”

About Genous Technology

Genous is OrbusNeich's patented EPC capture technology that 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.

The Genous Stent, which has been commercially available in more than 60 countries since 2005, has been proven as a safe, effective alternative to drug eluting stents and is supported by data from more than 7,000 patients in company-sponsored clinical studies. There is a growing body of evidence from multiple clinical studies that the Genous Stent is effective for patients who are non-responsive to or cannot tolerate long-term dual antiplatelet therapy.

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 pro-healing stent, the Genous Stent, as well as other stents and balloons marketed under the names of Azule™, R stent, Scoreflex™, Sapphire™, Sapphire II and Sapphire NC. Development stage products include the Combo Dual Therapy Stent, the only dual therapy stent to both accelerate endothelial coverage and control neo-intimal proliferation through the combination of the Genous pro-healing technology with an abluminal sirolimus drug elution. OrbusNeich is headquartered in Hong Kong and has operations in Shenzhen, China; Fort Lauderdale, Fla.; Hoewelaken, 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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