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COMBO™ Dual Therapy Stent demonstrates true tissue maturation with low clinical events rate out to 4 years at EuroPCR 2015

Paris, France [4th June 2015] OrbusNeich announced at the recent EuroPCR 2015 the long-term clinical outcomes and the first ever evidence of further tissue maturation following placement of the COMBO Dual Therapy Stent. COMBO is the world's first and only dual therapy stent designed to repair vessel injury and regenerate the endothelium, fostering natural, true vessel healing. It does this by accelerating endothelial coverage and controlling neointimal proliferation through a combination of sirolimus drug elution and OrbusNeich's unique endothelial progenitor cell (EPC) capture technology.

Further tissue maturation was observed from 9 to 24 months after COMBO implantation in support of the unique neointimal regression results from the EGO COMBO trial. "It is very exciting to see for the first time the correlation between tissue coverage and vessel healing under advanced imaging technology," said Dr Michael Joner, M.D., CEO, CVPath Institute, United States. "OCT technology allows us to visualize stent coverage despite limitations on the ability to differentiate nature of coverage with the current technology. From the evidence we see to date, COMBO is the only stent with active pro-healing properties which has demonstrated rapid endothelialization together with the ability to suppress neointimal proliferation."

The clinical results demonstrate that COMBO has low ischemic and thrombotic event rates. The REMEDEE first-in-man 4-year follow-up data showed no incidents of stent thrombosis, with clinically-driven target lesion revascularization remaining low at 7.3%.

“The COMBO Dual Therapy Stent has shown promising long-term clinical outcomes from data we see from the REMEDEE clinical trial. It has been shown to be safe, with an overall low rate of clinical events and no incidence of stent thrombosis to date. These promising data set the stage for larger randomized trials which have been planned to further demonstrate safety and efficacy of this innovative technology,” said Dr Roxana Mehran, M.D., Director of Interventional Cardiovascular Research and Clinical Trials, Mount Sinai Medical Center, United States.

The symposium also featured Dr Robbert J. de Winter, MD, AMC, The Netherlands, who explored the role of COMBO in the ongoing debate over the duration of dual antiplatelet therapy (DAPT). “DAPT duration should be dependent on the patient’s condition rather than on stent choice. COMBO’s early healing profile makes it the natural choice of stent when DAPT duration flexibility is required,” said Dr de Winter. “The ongoing clinical trial program, with over 7,000 patients enrolled, will further validate the benefits of COMBO Dual Therapy stent. I am particularly impressed with the REDUCE and COSTA trials which are specifically designed to assess duration of DAPT in a prospective fashion. COMBO may be the only stent with such data available”.

EuroPCR is the official congress of the EAPCI (European Association of Percutaneous Cardiovascular Interventions), held annually in Paris, which brings cardiologists from around the world together to discuss and to learn about the latest advances in cardiovascular disease.

COMBO Dual Therapy Stent - Repair, Regenerate, Naturally

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 capturing 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™, R Stent™, 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.

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