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## OrbusNeich Announces Enrollment of First Patient in China Recovery Study

*Study to enroll 436 patients at up to 20 sites throughout China*

**Hong Kong [20 July 2015**] OrbusNeich, a global company specializing in the provision of life-changing vascular solutions, has announced that the first patient has been enrolled in the clinical study in China of its COMBO™ Dual Therapy Stent. The China Recovery Study is designed to evaluate the COMBO Dual Therapy Stent compared to the Nano stent (Lepu Medical Technology Co, Ltd). The first patient was enrolled by Dr Yuan Ming at The First Affiliated Hospital of the Fourth Military Medical University in May 2015.

The study, a multi-center, prospective, non-inferiority, randomized controlled trial, will enroll 436 patients at up to 20 leading hospitals throughout China. "We are pleased to announce the enrollment and treatment procedure of the first patient with the COMBO stent and anticipate further enrollment to continue over the coming months," said Steve Rowland, Vice President Research & Development, OrbusNeich. "This trial will deliver significant data that will provide physicians with valuable knowledge to make the best treatment decisions for their patients in China and beyond."

The study will enroll patients with de novo stenotic lesions in native coronary arteries. Patients will be randomized 1:1 to the COMBO Dual Therapy Stent or the Nano stent, with follow up at 30 days, 6 months, 12 months and annually for up to 5 years. Additionally, Angiographic follow-up will be performed for all subjects at 9 months post-procedure. The principal investigator is Professor Tao Ling from the First Affiliated Hospital of the Fourth Military Medical University, Xian, China.

WHO figures estimate that one in five adults in China has a cardiovascular disease with numbers predicted to increase significantly in the coming years based on projected increased incidence of high blood pressure, diabetes, smoking and high cholesterol levels.
http://www.wpro.who.int/china/mediacentre/factsheets/cvd/en/

**Editor's notes**

**About the study**

Primary endpoint: In-segment late lumen loss (LLL) at 9 months post-procedure

Secondary endpoints include:

- Device, lesion and clinical success rates;
- The device-oriented target lesion failure (TLF) defined as a composite of cardiac death, target vessel myocardial infarction (MI), and ischemia-driven target lesion revascularization (i-TLR) at 30 days, 6 months, 12 months and annually up to 5 years follow-up;
- The patient-oriented composite endpoint, which includes all-cause death, all MIs, or any revascularization at 30 days, 6 months, 12 months and annually up to 5 years follow-up;
- In-stent LLL at 9 months post-procedure;
- In-stent and In-segment binary restenosis (BR) rates at 9 months post-procedure;
- In-stent and In-segment minimal lumen diameter (MLD) at 9 months post-procedure;
    - Definite and probable stent thrombosis (ST) in acute, sub-acute, late and very late period per Academic Research Consortium (ARC) definition criteria;

**About 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.

Learn more about our life-changing technologies on our social media channels:
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