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**OrbusNeich achieves double milestone in clinical trial program**  
*Studies involving over 1,000 patients complete enrolment at locations in Japan, US and China*

**Hong Kong [16 August 2016]** OrbusNeich, a global company specializing in the provision of life-changing vascular solutions, has announced that two major clinical studies have now completed enrolment. The studies – HARMONEE (Harmonized Assessment by Randomized, Multi-center Study of OrbusNEich’s COMBO StEnt) and RECOVERY – involve more than 1,000 patients at over 50 study locations throughout Japan, the United States and China.

Both studies are randomized trials comparing the COMBO™ Dual Therapy Stent (DTS) to market leaders. The HARMONEE study is being conducted to demonstrate the effectiveness of COMBO compared to the Abbott Vascular Xience stent in the treatment of significant ischemic heart disease. HARMONEE is being carried out under the framework of the joint Japan-US Harmonization-By-Doing (HBD) initiative and will support the company’s planned application for approval in Japan and to meet the feasibility trial requirements in the US. The RECOVERY study is designed to evaluate the COMBO DTS compared to the Nano stent from Lepu Medical Technology and will be used to support the submission for market approval in China. One-year results from both trials are expected in the second half of 2017.

“We are pleased to have completed enrolment on four significant trials so far this year,” said B Wayne Johnson, President and Chief Executive Officer, OrbusNeich. “The HARMONEE and RECOVERY studies follow the MASCOT registry and REDUCE trial, both of which completed enrolment last spring. With over 7,000 patients documented in our COMBO clinical program, we are well placed to build further compelling evidence for COMBO as well as gaining market approval in the major markets of China and Japan.”

## **Notes to Editor**

### **The HARMONEE study [NCT02073565]**

The HARMONEE study is a multi-center, single-blind, randomized, active-controlled, clinical trial in Percutaneous Coronary Intervention (PCI) subjects, with 572 patients at 50 study locations in Japan and the US. Subjects are randomized to receive the COMBO stent as the investigational treatment arm or an EES as the active-control arm. The study's primary endpoint is a comparison at 12-months of clinically driven target vessel failure (TVF), defined as cardiac death, target vessel myocardial infarction (MI) or ischemia-driven target vessel revascularization (TVR) by percutaneous or surgical methods.

### **The RECOVERY study [NCT02542007]**

The RECOVERY study is a multi-center, prospective, non-inferiority, randomized controlled trial, with 436 patients with de novo stenotic lesions in native coronary arteries enrolled at 16 leading hospitals throughout China. Patients are 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 study's endpoint is in-segment late lumen loss at nine months post-procedure.

### **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. 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 proprietary 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 coronary stents and balloons marketed under the names of Azule™, Scoreflex™, Sapphire™ II, Sapphire™ II Pro, Sapphire™ II NC and peripheral balloons JADE™ and Scoreflex™ PTA . 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](http://www.OrbusNeich.com).

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