Global Media Contacts:
Christine Lydon
+44-20-7395-7145
christine.lydon@fleishmaneurope.com
Iva Ng
OrbusNeich
+852 3109-7268
ing@orbusneich.com

OrbusNeich Announces Initiation of HARMONEE Stent Study in US

Registration study to enroll 572 patients at up to 50 study locations in Japan and US

Hong Kong [18 May 2015] OrbusNeich, a global company specializing in the provision of life-changing vascular solutions, has announced that the first US patient has been enrolled in the HARMONEE (Harmonized Assessment by Randomized, Multi-center Study of OrbusNEich's COMBO StEnt) stent study. The study is being conducted under the framework of the joint Japan-US Harmonization-By-Doing (HBD) initiative and will support the company's planned application for Shonin approval in Japan and to meet the feasibility trial requirements in the US.

"We are delighted to confirm that the enrollment process for the HARMONEE study in the US has begun," said Steve Rowland, Vice President Research & Development, OrbusNeich. "With a unique Japan-US collaboration involving co-enrollment in both countries and a single Japan-US protocol, this regulatory harmonization will help bring forward new options for patients with coronary artery disease in both countries."

The study is a multi-center, single-blind, randomized, active-controlled, clinical trial in Percutaneous Coronary Intervention (PCI) subjects. Several additional sites are open and actively screening.

The HARMONEE study will enroll 572 patients at up to 50 study locations in Japan and the US. The first patient was enrolled at Shonan Kamakura General Hospital, Japan in February 2014. The study's endpoint is a comparison 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. All patients will undergo fractional flow reserve (FFR) or angiography to determine ischemia-driven TVR.

“The enrollment of the first US patient marks a key milestone in the initiation of the US Investigational Device Exemption portion of the HARMONEE study,” said Dr Roxana Mehran, M.D., Director of Interventional Cardiovascular Research and Clinical Trials, Mount Sinai Medical Center, United States, and US Principal Investigator. “This randomized controlled trial is the first to use both physiologic and anatomic assessment of the long-term result of the stent procedure, as well as using high-resolution imaging of vascular healing, and it will provide important data that will inform the care of patients with coronary artery 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.

Learn more about our life-changing technologies on our social media channels:
Twitter: www.twitter.com/OrbusNeich

LinkedIn: www.linkedin.com/company/orbusneich-medical
YouTube: http://www.youtube.com/user/OrbusNeichMedia

###