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Global Media Contacts:

David Schull or Lena Evans
Russo Partners
+1 212-845-4271
+1 212-845-4262
david.schull@russopartnersllc.com
lena.evans@russopartnersllc.com

David Kujawa
OrbusNeich
+1 954-730-0711 (office)
+1 305-733-7216 (mobile)
dkujava@orbusneich.com

First Patients Enrolled in REMEDEE Registry to Evaluate Long-Term Safety and Performance of OrbusNeich’s COMBO Dual Therapy Stent™ in Routine Practice

Multicenter, All-Comers, Post-Market Registry to Enroll 1,000 Patients at Nine European Sites

HONG KONG, August 6, 2013 – Patient enrollment has been initiated in a post-market registry for the COMBO Dual Therapy Stent to evaluate its long-term safety and performance in routine clinical practice. The prospective, multicenter, all-comers REMEDEE Registry (Multicenter, Prospective, Clinical Outcomes After Deployment of the Abluminal Sirolimus Coated Bio-Engineered Stent (Combo Bio-Engineered Sirolimus Eluting Stent) Post Market Registry) will enroll 1,000 patients at nine European sites. As of today, more than 100 patients have already been enrolled.
Study sites will consecutively enroll patients in whom COMBO Stent placement is attempted to treat a coronary lesion in the setting of routine clinical care. This flash-type patient recruitment will include 100 to 150 patients at each of the participating nine high-volume percutaneous coronary intervention centers in France, Latvia, Luxembourg, The Netherlands, Northern Ireland and Spain.

The primary endpoint is clinically driven target vessel failure (TVF) at one year post procedure, which includes cardiac death, target vessel myocardial infarction (MI) and ischemia driven target vessel revascularization (TVR). Primary endpoint data are expected in the first quarter of 2015.

“The COMBO Dual Therapy Stent is a truly innovative device that addresses the challenge of delayed arterial healing caused by monotherapy drug eluting stents by combining the antiproliferative property of a drug eluting stent with a pro-healing antibody coating technology,” said Robbert de Winter, M.D., Ph.D., of the Academic Medical Center, Amsterdam, and principal investigator of the study.

Robert N. Wood, Jr., senior vice president and chief commercial officer of OrbusNeich, said, “Now that CE Mark has been received for the COMBO Dual Therapy Stent, the REMEDEE Registry will help to establish the long-term safety and performance for the COMBO Stent in a real-world patient population.”

Secondary endpoints include device and procedural success and adjudicated target lesion failure (TLF) at 30 and 180 days post procedure. Additional secondary endpoints to be evaluated at 30, 180 and 365 days include the components of TVF, defined as cardiac death, target vessel MI and ischemia driven TVR; adjudicated major adverse cardiac events (MACE) as a composite and as each of its components, defined as death, any MI and any revascularization; and adjudicated stent thrombosis. Clinical follow-up will be conducted each year up to five years.

For more information about the REMEDEE Registry, please visit http://www.clinicaltrials.gov/ct2/show/NCT01874002.
About the COMBO Dual Therapy Stent

The COMBO Dual Therapy Stent is the first dual therapy stent to both accelerate endothelial coverage and control neo-intimal proliferation through the combination of the proven pro-healing technology with an abluminal sirolimus drug elution delivered from a biodegradable polymer that achieves full and complete dissipation by 90 days.

OrbusNeich’s patented 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

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 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™, Sapphire II and Sapphire NC. OrbusNeich is headquartered in Hong Kong and has operations in Shenzhen, China; Fort Lauderdale, Fla.; 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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