Randomized Clinical Trial of OrbusNeich’s Genous™ Bio-engineered R stent™ in China Completes Patient Enrollment

HONG KONG, Oct. 11, 2010 – OrbusNeich today reported the completion of patient enrollment in a randomized clinical study of its Genous Bio-engineered R stent at 11 sites in China.

The primary objective of the 180 patient, controlled study is to demonstrate the safety and effectiveness of the Genous Bio-engineered R stent compared to the Medtronic Endeavor® Sprint stent in patients with symptoms of angina or myocardial ischemia. The primary endpoints are difference in Major Adverse Cardiac Event (MACE) rates between the two groups at 12 months after implantation and 270 day angiographic Late Loss (LL). Patients enrolled in the study were split evenly between the control and test arms.
“Based on its unique design and healing technology, we believe that Genous has the potential to give physicians an additional option for treating patients,” said Prof. Lu Shuzheng from Anzhen Hospital, principal investigator of the trial. “We are excited to complete enrollment in this study, which may bring further clinical support for the technology’s use in China.”

David Chien, vice chairman of OrbusNeich, added, “This first clinical study of Genous in China is significant in the full development of the technology. We look forward to seeing additional clinical support for the use of Genous in challenging cases, such as diabetic patients and those who cannot tolerate a year of dual antiplatelet therapy.”

Secondary endpoints include all-cause and cardiac mortality, myocardial infarction, in-stent thrombosis, MACE rates at 30, 60, 90, 180 and 270 days, as well as clinically driven Target Lesion Revascularization (TLR), Target Vessel Revascularization (TVR) and Target Lesion Failure (TLF) rates at 30, 60, 90, 180, 270 and 360 days.

**About Genous**

Genous is OrbusNeich’s patented endothelial progenitor cell (EPC) capture technology that 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.

OrbusNeich’s Genous Bio-engineered R stent has been commercially available in over 60 countries since 2005. The Genous stent has been proven as a safe, effective alternative to drug-eluting stents and is supported by data from more than 5,000 patients in company-sponsored clinical studies. There is a growing body of evidence from multiple clinical studies that the Genous stent is effective for patients who are non-responsive to or cannot tolerate long-term dual antiplatelet therapy.
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 pro-healing stent, the Genous Bio-engineered R stent, as well as other stents and balloons marketed under the names of Blazer™, R stent, Scoreflex™, Sapphire™, and Sapphire NC. Development stage products include the Combo™ Bio-engineered Sirolimus Eluting Stent, or Combo Stent, which combines the Genous pro-healing technology for rapid endothelial coverage with an abluminal sirolimus drug elution for the control of neointimal proliferation. OrbusNeich is headquartered in Hong Kong and has operations in Shenzhen, China; Fort Lauderdale, Fla.; Hoevelaken, The Netherlands; and Tokyo, Japan. OrbusNeich, which has provided medical devices to physicians through its predecessor companies since 1979, supplies products today to interventional cardiologists in more than 60 countries. For more information, visit www.OrbusNeich.com.

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