# Data Presented at ACC.12 Demonstrate that OrbusNeich's GenousT Stent Is Feasible and Safe in STEMI Patients

The Associated Press

OrbusNeich today announced that three-year clinical results presented at the American College of Cardiology's (ACC's) 61st Annual Scientific Session & Expo, ACC.12, demonstrate the safety and feasibility of the Genous Stent for patients with ST-segment elevation myocardial infarction (STEMI) and showed no incidence of very late stent thrombosis (ST). Additional analyses from the REMEDEE trial for OrbusNeich's Combo Dual Therapy Stent were also featured at the congress.

For the study in STEMI patients, the primary endpoint was the rate of major adverse cardiac events (MACE), defined as death, myocardial infarction (MI), target vessel revascularization (TVR) and ST, between one and three years. The MACE rate at three years was 20.1 percent, driven predominantly by cardiac death and MI; after patients with cardiogenic shock were excluded, the MACE rate was 15.5 percent.

Importantly, no incidence of ST was observed between one and three years. The prospective study included 384 STEMI patients treated with the Genous Stent, of which 7.2 percent had cardiogenic shock and 33.1 percent had diabetes.

"The absence of stent thrombosis between the first and third years is particularly impressive in this high-risk patient population," said Huay Cheem Tan, M.B.B.S., of the National University Hospital in Singapore, the study's principal investigator. "The use of drug eluting stents in the setting of primary percutaneous coronary intervention (PCI) has generated some concern in the past, and the Genous Stent's good safety profile despite only one month of dual antiplatelet therapy makes it an attractive alternative in this situation." New analyses from the REMEDEE trial were also presented at ACC.12 and compared angiographic and intravascular ultrasound (IVUS) endpoints for the Combo Dual Therapy Stent versus the TAXUS@ Liberte@ paclitaxel-eluting stent. The data showed qualitative and quantitative differences between the two stents, specifically in the pattern of in-stent late lumen loss at nine months.

"These analyses attest to the clinical differences between the monotherapy approach of drug elution alone and the dual therapy approach of Combo, which combines drug elution with the pro-healing Genous technology," said Michael Haude, M.D., director of Medical Clinic I at the Lukaskrankenhaus in Neuss, Germany, and the REMEDEE trial's principal investigator. "First, we observe a tighter distribution of in-stent late lumen loss for the Combo Dual Therapy Stent versus a bimodal distribution for the TAXUS Liberte stent.

Second, we see that the restenosis pattern of recurrence for the Combo Dual Therapy Stent is more focal compared to TAXUS, which is more diffuse. These

results help us to understand the two different approaches more clearly." Nine-month clinical outcomes from the REMEDEE study were previously presented at TCT 2011 (News Release, Nov. 14, 2011), confirming that the Combo Dual Therapy Stent was non-inferior to the TAXUS Liberte stent with respect to in-stent late lumen loss at nine-month angiographic follow-up.

About the Genous Technology Genous is OrbusNeich's patented 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 attracts EPCs circulating in the blood to the device to form an endothelial layer that provides protection against thrombosis and modulates restenosis.

The Genous Stent, which has been commercially available in more than 60 countries since 2005, has been proven as a safe, effective alternative to drug eluting stents and is supported by data from more than 7,000 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 Stent, as well as other stents and balloons marketed under the names of AzuleT, R stent, ScoreflexT, SapphireT, Sapphire II and Sapphire NC. Development stage products include the Combo Dual Therapy Stent, the only dual therapy stent to both accelerate endothelial coverage and control neo-intimal proliferation through the combination of the Genous pro-healing technology with an abluminal sirolimus drug elution. 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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