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Data from Multiple Clinical Trials of OrbusNeich's Genous™ Bio-engineered R Stent™ Demonstrate Safety and Effectiveness Across Challenging Patient Subsets as Presented at TCT 2010

Genous EPC Capture Technology Featured in Symposium

WASHINGTON, Sept. 25, 2010 – OrbusNeich today announced that clinical trial results highlighting the company's Genous Bio-engineered R stent and its endothelial progenitor cell (EPC) capture technology across challenging patient subsets were presented during a symposium titled "EPC Capture Technology: from Genous to Combo" at Transcatheter Cardiovascular Therapeutics (TCT) 2010 in Washington.

Genous Bio-engineered R stent is safe and effective in diabetic patients, elderly patients and in patients who stopped dual antiplatelet therapy (DAPT)

at 30 days and at six months due to increased risk for bleeding or DAPT cessation.

Professor Robbert de Winter, M.D., Ph.D., of the Academic Medical Center in Amsterdam presented a subset analysis from the global e-HEALING registry. The findings included:

- Twelve-month follow-up data that compared results from 339 elderly patients over the age of 80 to 4,584 patients under the age of 80 showed that the elderly patients had significantly more risk factors such as hypertension and acute coronary syndrome (ACS) and presented with more complex lesions. Compared to the younger cohort, elderly patients had higher rates of target vessel failure (TVF) driven mainly by cardiac death. Significantly, the rate of late stent thrombosis at 12 months in elderly patients (0.3 percent) was shown to be low and similar to that of the younger patient group (0.2 percent).
- Twelve-month outcomes were shown to be similar between patients who stopped DAPT at 30 days and those who continued on DAPT; the TVF rates of the two subgroups were 6.3 percent and 6.5 percent, respectively. The subset analysis also showed that 12-month outcomes were similar between patients who stopped DAPT at six months and those who continued; the TVF rates of the two subgroups were 2.8 percent and 2.4 percent, respectively. Both patient subgroups showed a low definite or probable stent thrombosis similar to the corresponding control groups.

Professor de Winter, a co-principal investigator of the study, said, “The e-HEALING data demonstrate the safety and excellent clinical outcome profile of the Genous Bio-engineered R stent in elderly patients and patients on only one month of DAPT.”

e-HEALING is a multi-center, worldwide (outside of the United States) prospective clinical registry conducted in 31 countries at 144 clinical centers.

Genous Bio-engineered R stent demonstrates effectiveness and safety and does not increase risk of in-stent thrombosis in patients with non-ST-segment elevation acute coronary syndrome (NSTEMI-ACS).

Professor Wojciech Wojakowski, M.D., of the Third Division of Cardiology, Katowice, Poland, presented 12-month follow-up results from the JACK-EPC clinical trial, an investigator-initiated, randomized trial that compared the Genous Bio-engineered R stent with bare metal stents (BMS) in 60 patients with NSTEMI-ACS. The results showed:

- The major adverse cardiac event (MACE) rate in Genous Bio-engineered R stent treated patients was 13.3 percent compared to 23.3 percent in BMS patients, and no in-stent thrombosis was apparent in either cohort at 12-month follow-up.
- At six months, the in-stent late loss in the Genous Bio-engineered R stent treated patient group was 0.45 mm compared to 0.86 mm in the BMS treated group, and the binary restenosis rate was 13 percent versus 26.6 percent, respectively.

The primary endpoints of the study were in-stent loss and binary restenosis. MACE was defined as cardiovascular death, myocardial infarction and any hospitalization for ACS.

“The 12-month results show that the Genous Bio-engineered R stent induces less neointimal hyperplasia than bare metal stents,” said Professor Wojakowski. “These data confirm that Genous is safe and effective in patients with ACS with no stent thrombosis.”

Genous Bio-engineered R stent shows complete endothelialization in majority of patients at 30 days post-implantation.

Dr. Pasi Karjalainen, M.D., Ph.D., of the Satakunta Central Hospital in Pori, Finland, presented 30-day follow-up optical coherence tomography (OCT) evaluations from 13 patients treated with the Genous Bio-engineered Cobalt Chromium Stent. The findings showed:

- Out of 2224 stent struts, 96 percent analyzed were completely covered at 30 days.
- The Doppler assessment of coronary flow velocity (CFR) demonstrated a functional endothelium at 30 days in almost all patients.

Dr. Karjalainen commented, “The complete endothelialization at 30 days in patients treated with the Genous stent demonstrates the ability of the EPC capture technology to accelerate the body’s natural healing process.”

Al Novak, Chairman and CEO of OrbusNeich, added, “The extensive clinical data sets presented today further support the use of the Genous Bio-engineered R stent as a safe and effective treatment option in challenging cases.”

The symposium, which was chaired by Professor Dr. Sigmund Silber, M.D., Ph.D., of the Kardiologische Klinik Dr Müller, Munich, also featured a presentation about OrbusNeich’s next generation Combo™ Bio-engineered Sirolimus Eluting Stent (Combo Stent). Professor Michael Haude, M.D., of Medical Clinic I at the Lukaskrankenhaus in Neuss, Germany, presented “The Future in DES: Combo.”

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 attracts 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 stents, balloons and guiding catheters 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.; Hoewelaken, 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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