OrbusNeich's GenousT Stent Is Safe and Effective in Patients Who Discontinue Dual Antiplatelet Therapy (DAPT) Within 15 Days of Stent Placement

The Associated Press

New clinical data published in the International Journal of Cardiologysupports that OrbusNeich's Genous Stent is safe and effective in patients who discontinue DAPT within 15 days of stent placement. Specifically, no differences in rates of stent thrombosis (ST) and other clinical outcomes were observed between patients who discontinued DAPT prior to and after 15 days, according to the results of ARGENTO, a consecutive, prospective study in 384 patients undergoing single or multivessel percutaneous coronary intervention (PCI) with the Genous Stent.

In the study, the rate of major adverse cardiac events (MACE) in all patients at follow up (22.8 +/- 13.6 months) was 8.6 percent. The rate of cardiac death was 3.4 percent, and myocardial infarction (MI) similarly occurred in 3.4 percent of patients. In addition, the rate of target vessel revascularization (TVR) was 4.7 percent. The overall rate of definite or probable stent thrombosis (ST) was 1.3 percent.

Although not statistically significant, the rates of MACE (4.4 percent for discontinued DAPT; 9.9 percent for continued DAPT) and TVR (1.1 percent for discontinued DAPT; 5.8 percent for continued DAPT) were lower in the patient group that received a shorter duration of DAPT.

Definite or probable ST occurred in 1.1 percent of patients who discontinued DAPT prior to or at 15 days and in 1.3 percent of patients who received DAPT beyond 15 days.

"In patients treated with the Genous Stent, DAPT duration does not appear to predict risk for fatal events, such as ST or MI, typically associated with the premature discontinuation of antiplatelet agents following treatment with a stent," said Federico Piscione, M.D., of the Federico II University in Naples, Italy, and corresponding author of the publication. "In fact, we observe a trend toward improved outcomes for patients who discontinue DAPT within 15 days of stenting.

Taken together, these data suggest that the Genous Stent is a safe and effective option for patients with expected or known low compliance to long-term DAPT." The consecutive, prospective study enrolled 384 patients who underwent single or multivessel percutaneous coronary intervention (PCI) with Genous Stent implantation; a total of 423 lesions were treated.

Ninety-one patients discontinued DAPT within 15 days, while 293 received DAPT for more than 15 days. Of the patients treated, 30.5 percent were diabetics, 37.5

percent had history of previous MI, and 58.8 percent had a history of acute coronary syndrome (ACS), including unstable angina, non ST-elevation myocardial infarction (NSTEMI) and ST-elevation myocardial infarction (STEMI).

Paolo Scacciatella, M.D., of the Department of Cardiovascular and Thoracic Diseases, S. Giovanni Battista University Hospital, Turin, Italy, and a co-author of the publication, said, "The ARGENTO results confirm the safety and efficacy of the Genous Stent when combined with a very short duration of DAPT. These data are similar to those in previous studies that suggest that the Genous Stent may also be an important alternative for high-risk patients and for those undergoing undeferrable non-cardiac surgery." About the Genous Technology 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.

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 8,000 patients in clinical studies. There is a growing body of evidence from multiple clinical studies that the Genous Stent is effective for patients that 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 StentT, 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 delivered from a biodegradable polymer that achieves full and complete dissipation by 90 days. 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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International Journal of Cardiology ST: Hong Kong IN: HEA MEQ MTC SU: SVY PRN -- FL28336 -- 0000 06/21/2012 13:00:00 EDT http://www.prnewswire.c

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