Patient Enrollment Completed in First Randomized Clinical Study of OrbusNeich's Combo™ Bio-engineered Sirolimus Eluting Stent

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WASHINGTON, Sept. 24 /PRNewswire/ -- OrbusNeich today announced at the Transcatheter Cardiovascular Therapeutics (TCT) 2010 in Washington the completion of patient enrollment in the randomized clinical trial of the Combo Bio-engineered Sirolimus Eluting Stent (Combo Stent) with 183 patients included at sites in Asia, Australia, Europe and South America.

"Completion of enrollment of this study represents a significant milestone as we look to validate the potential for the Combo Stent in a clinical setting," said Al Novak, Chairman and CEO of OrbusNeich.

The primary objective of the prospective, randomized, multicenter study, called REMEDEE (**R**andomized **E**valuation of an ablu**M**inal sirolimus coat**ED** bio-**E**ngineered st**E**nt), is to demonstrate safety and effectiveness of the Combo Stent compared to the TAXUS® Liberte® paclitaxel-eluting stent in patients with symptomatic, ischemic heart disease due to a stenotic lesion located in a native coronary artery. This objective will be measured in patients by a comparison of in-stent late lumen loss at nine months post-procedure.

Michael Haude, M.D., director of Medical Clinic I at the Lukaskrankenhaus in Neuss, Germany, and one of the trial's principal investigators, added, "The Combo Stent has the potential to bring a unique treatment option to physicians by combining the proven Genous endothelial progenitor cell capture technology with a low dose sirolimus elution. Because the pre-clinical data demonstrate lower neointimal hyperplasia and improved endothelial coverage, we look forward to obtaining clinical confirmation of the results."

Secondary endpoints include all-cause and cardiac mortality, myocardial infarction, Major Adverse Cardiac Event (MACE) and stent thrombosis rates at 30 days, nine months and one through five years, as well as clinically driven Target Lesion Revascularization (TLR), Target Ves
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