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Global Media Contact:
Alain Khair +31332541150

OrbusNeich's COMBO Plus dual therapy stent shows very low stent thrombosis and consistent endothelial coverage at 5 years

Final results from the REMEDEE Registry and FUNCOMBO study reported at the PCR e-Course 2020

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The PCR e-Course held on June 25-27th, the virtual on-line version of the EuroPCR 2020, gave the opportunity for presentation of additional clinical evidence of the long-term clinical performance and safety of the dual therapy endothelial progenitor cell-capturing sirolimus-eluting COMBO Plus stent. Two late-breaking presentations were given for the mechanistic FUNCOMBO study and the final 5-year results for the 1000 patient all-comers REMEDEE Registry, respectively.

The 5-year follow-up results from the multi-center 1000 patient REMEDEE Registry were presented by Dr Laura Kerkmeijer from the Academic Medical Center, University of Amsterdam, The Netherlands. The occurrence of definite/probable stent thrombosis from the registry of all-comers, with a patient population of 49.8 % ACS, showed a stent thrombosis rate of 0.9 % with only 9 patients presenting with ST in the 5 years follow-up, of which 6 ST cases occurred within the first 9 days. This is the first report of the long-term clinical performance and safety of the COMBO Plus stent in an all-comers patient population, which show excellent durability of the clinical results over five years with a low rate of revascularization and a remarkably low rate of late and very late stent thrombosis.

The final results from the FUNCOMBO study, a comparison of the six-month functional assessment of infarct-related arteries treated with dual-therapy endothelial progenitor cell-capturing sirolimus-eluting COMBO Plus stent versus the polymer-free biolimus A9-eluting BioFreedom stent, were presented by Dr Josep Gomez-Lara from Hospital Universitari de Bellvitge, Institut d' Investigació Biomèdica de Bellvitge, Universitat de Barcelona, L' Hospitalet de Llobregat, Spain. In this 60 patient mechanistic study at six months after the treated patients presented with a ST-segment myocardial infarction, the COMBO Plus stent was found to have similar endothelial-mediated vasomotion function to the BioFreedom stent, while demonstrating adequate control of neointimal proliferation with better stent strut apposition, less evidence of neoatherosclerosis, and improved stent strut neointimal coverage with the COMBO Plus stent.

“The 5-year REMEDEE Registry long-term result of the stent thrombosis and lesion revascularization showed durability of clinical effectiveness of the dual therapy COMBO Plus stent” stated Mr. Alain Khair, OrbusNeich Senior Vice President and Chief Commercial Officer. “The FUNCOMBO study provides important new mechanistic validation of the EPC-capturing stent functionality. These results have shown consistence with the already substantial body of mechanistic evidence seen in REMEDEE OCT, EGO-COMBO and HARMONEE.”

About the COMBO Plus Coronary Stent

The COMBO Plus Coronary Stent is the first stent to combine a proprietary endothelial progenitor cell [EPC] capture technology on the luminal stent surface with an abluminal sirolimus drug elution delivered from a biodegradable matrix polymer that is completely dissipated within 90 days. OrbusNeich's patented EPC capture technology consists of an immobilized antibody surface coating that captures EPCs circulating in the blood to the device surface.

About OrbusNeich – Pioneers in life-changing technologies

OrbusNeich is a global pioneer in the provision of life-changing vascular solutions and offers an extensive portfolio of products that set industry benchmarks in vascular intervention. Current products are the COMBO® PLUS Coronary Stent, together with stents and balloons marketed under the names of AZULE®, SCOREFLEX®, SCOREFLEX® NC, SAPPHIRE® II PRO and SAPPHIRE® II NC, SAPPHIRE® NC Plus and the TELEPORT® microcatheter, as well as products to treat peripheral artery disease: the JADE® and SCOREFLEX® PTA balloons. OrbusNeich is headquartered in Hong Kong and has operations in Shenzhen, China; Fort Lauderdale, Florida, USA; Hoevelaken, The Netherlands; and Tokyo, Japan. OrbusNeich supplies medical devices to physicians in more than 60 countries.

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