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OrbusNeich® Announces China Approval for COMBO® Coronary Stent

HONG KONG [23rd September 2020] – OrbusNeich Medical Co. Ltd. has announced that the National Medical Products Administration (NMPA) has granted market approval for the COMBO BIO-ENGINEERED SIROLIMUS ELUTING STENT in China. It is the first dual therapy stent to both accelerate endothelial coverage and control neointimal proliferation through the combination of the proven pro-healing technology with an abluminal sirolimus drug elution delivered from a biodegradable polymer that achieves full and complete dissipation by 90 days.

OrbusNeich's patented endothelial progenitor cell (EPC) capture technology 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 captures EPCs circulating in the blood to the device to form an endothelial layer that provides protection against thrombosis and modulates restenosis.

“The market approval of the COMBO Stent in the People’s Republic of China is a strategically important success for the OrbusNeich organization as we further expand into significant territories”, said David Chien, OrbusNeich’s Chairman, President and CEO. “We expect the approval of a unique product such as the COMBO Stent to allow OrbusNeich to strengthen our presence in China alongside our existing PTCA and PTA portfolio.”

The ongoing randomized, multi-center RECOVERY trial [NCT02542007] comparing the COMBO Stent with the polymer-free sirolimus-eluting Nano stent (PF-SES) (Lepu Medical Technology, Beijing, China) in the treatment of patients with de novo native coronary artery lesions provided clinical data supporting the approval. A total of 432 patients were enrolled at 16 centers in China and randomized one-to-one to the treatment with COMBO Stent or the treatment with PF-SES. In this positive trial, the COMBO Stent was found to be non-inferior in the study primary endpoint of 9-month angiographic in-segment late lumen loss compared to the PF-SES, with in-segment LLL of 0.29 ± 0.46 mm and 0.31 ± 044 mm respectively (p = 0.57). At 1-year, clinical outcomes were similar between the groups for target lesion failure (TLF), a composite of cardiac death, target-vessel myocardial infarction, or ischemia-driven target lesion revascularization, and all TLF components. There was no stent thrombosis in either group.

“Since its launch, the COMBO Stent has played an important role in helping patients with coronary artery disease,” said Senior Vice President and Chief Commercial Officer, Alain Khair. “The COMBO Stent, with its unique pro-healing properties, is another example of OrbusNeich’s commitment to providing innovative best-in-class devices to our physicians and their patients.”

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 Stent, together with stents and balloons marketed under the names of COMBO Plus, AZULE®, SCOREFLEX®, SCOREFLEX® NC, SAPPHIRE® II PRO, SAPPHIRE® 3 and SAPPHIRE® II NC, 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. For more information, visit www.OrbusNeich.com