

OrbusNeich COMBO® Coronary Stent approved in China

24 September 2020 | News

With the approval of a unique product, the COMBO Stent company allows OrbusNeich to strengthen its presence in China alongside existing PTCA and PTA portfolio



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 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 ± 0.44 mm respectively ($p = 0.57$). "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."