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COMBO® Plus Dual Therapy Stent Receives CE Mark Approval to Update DAPT Labeling

Opportunity for DAPT flexibility in SCAD and ACS patients unable to conform to treatment guidelines supported by recent clinical trial results

Hong Kong [April 23, 2018] OrbusNeich has received regulatory approval to update the CE Mark labeling for COMBO Plus Dual Therapy Stent with important new information on Dual Antiplatelet Therapy [DAPT] usage after Percutaneous Coronary Intervention [PCI] in the treatment of Stable Coronary Artery Disease [SCAD] and Acute Coronary Syndrome [ACS] patients based on recently released clinical trial results. The updated labeling indicates:

> *"Patients should comply with the dual antiplatelet therapy (DAPT) regimen as recommended by the latest ACC/AHA/SCAI and ESC guidelines. However, under circumstances during which standard DAPT duration is contraindicated or has to be balanced with (a high risk of) bleeding, physicians may consider early DAPT interruption or discontinuation:*
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> - *In patients with Acute Coronary Syndrome (ACS), physicians may consider a DAPT regimen as short as 3 months.*
> - *In Stable Coronary Artery (SCAD) patients, physicians may consider a DAPT regimen as short as 1 month."*

The updated labeling information is derived from the combined clinical outcomes from the prospective, randomized REDUCE Study in 1500 ACS patients and from the REMEDEE Registry ACS subgroup analysis in 498 patients which demonstrate the safety profile of the COMBO Stent in the treatment of ACS patients. Additionally, data from the "all comers" 1,000 patient REMEDEE Registry and the 2,614 patients in the MASCOT registry have shown the safety of the COMBO Stent in SCAD with a low risk of stent thrombosis with as little as one month of DAPT.

Consistent with the recognized need for individualized treatment with PCI patients, this new, well supported clinical information provides physicians with a unique option of flexibility in considering a shorter dual antiplatelet regimen for those patients for whom the standard DAPT duration is contraindicated or other medical conditions may require DAPT interruption or discontinuation. The updated label of a minimum of 3 months DAPT in ACS patients is the shortest recommended minimum duration for DAPT referenced on the label for this patient subset on any device of its kind.

“OrbusNeich continues to be committed to a robust clinical program involving over 9000 subjects designed to demonstrate the clinical utility of the COMBO” said Scott Addonizio, OrbusNeich Sr. Vice-President and COO. “Being able to incorporate these important updates into our COMBO labeling provides flexibility for physicians as they consider individualized treatments for their patients requiring PCI due to SCAD or ACS.”

About COMBO - There are multiple design features that make COMBO a unique and effective option for treating coronary stenosis. Following implantation, an exclusive biological coating on the outer surface of the COMBO immediately captures circulating endothelial progenitor cells from the blood and initiates the formation of an endothelial layer. This accelerated healing process, leads to earlier return of endothelial functionality. Together with the biological layer, a directional coating of bioabsorbable polymer elutes sirolimus to inhibit neointimal hyperplasia. This unique design combines accelerated healing with the effective control of restenosis.

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 world's first dual therapy stents, the COMBO Plus and COMBO Dual Therapy Stents, together with stents, balloons microcatheter marketed under the names of Azule®, Scoreflex®, Scoreflex® NC, Sapphire® II, Sapphire® II PRO and Sapphire® II NC, Teleport™ and Teleport™ Control 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