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First patient enrollment in MASCOT registry represents major milestone for COMBO™ Dual Therapy Stent and OrbusNeich’s clinical program

2,500-patient, 50-center study is the largest post-marketing registry on the safety and effectiveness of the COMBO Stent

HONG KONG, July 16, 2014 – OrbusNeich today announced that the first patient has been enrolled in the Multinational Abluminal Sirolimus Coated BiO-Engineered StenT (MASCOT) post-marketing registry. The first COMBO™ Dual Therapy Stent implant was performed at the Amphia Hospital in Breda, The Netherlands.

Designed to assess the long-term safety and effectiveness of the COMBO Stent in routine clinical practice, the prospective, multicenter registry is the largest clinical study of the unique dual therapy stent to date, with a goal of 2,500 patients being followed for a year in up to 50 centers across Asia and Europe.

The study’s primary endpoint is device-oriented target lesion failure (TLF), defined as the composite of cardiac death, non-fatal heart attack (myocardial infarction or MI) not clearly attributable to a non-target vessel, or target lesion revascularization (TLR) from enrollment to 12 months.
The principal investigator is Prof. Antonio Colombo, M.D., San Raffaele Hospital, Milan, Italy; the director of the clinical coordinating center is Roxana Mehran, M.D., Mount Sinai Medical Center.

“Long-term safety remains an important area of clinical investigation with stents, particularly the avoidance of neoatherosclerosis and late stent thrombosis,” said Prof. Colombo. “The MASCOT registry will provide important information about the unique dual therapy approach of the COMBO Stent, which offers the possibility of functional arterial vessel healing, which we have not seen with any of the monotherapy drug eluting stents.”

“The clinical data gathered from COMBO stent trials to date show promise with respect to long-term safety and efficacy,” added Dr. Mehran. “For example, target lesion revascularization remained stable at 5.7 percent in both years two and three of the REMEDEE trial, with no thrombotic events over three years. If those results hold in the MASCOT registry, that will be good news for patients and cardiologists.”

OrbusNeich is supporting the COMBO Stent with one of the industry’s most robust clinical programs. In addition to the MASCOT registry, the REDUCE trial – which enrolled its first patient in June 2014 – aims to demonstrate the potential for a shorter period of dual antiplatelet therapy. Find more information on REDUCE here.

“The initiation of MASCOT, our largest registry trial to date, represents the commitment we have made to really understand the patient benefits of the COMBO Stent,” said B. Wayne Johnson, president and chief operating officer, OrbusNeich. “Only by delivering true vessel healing can patients feel safe for the long term. We expect the MASCOT trial to confirm what we have already seen with the COMBO Stent as it relates to vessel healing.”

**About the COMBO Dual Therapy Stent**

The COMBO Dual Therapy Stent is the first dual therapy stent to both accelerate endothelial coverage and control neo-intimal proliferation through the combination of the proven Pro-Healing Technology with an abluminal sirolimus drug elution delivered from a biodegradable polymer that is completely dissipated within 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.

**About OrbusNeich**

OrbusNeich is a global company that designs, develops, manufactures and markets innovative medical devices for the treatment of vascular diseases. Current products are the world's first dual therapy stent, the COMBO Dual Therapy Stent, and the world’s first pro-healing stent, the Genous™ Stent. Other products include stents and balloons marketed under the names of Azule™, R stent, Scoreflex™, Sapphire™, Sapphire II and Sapphire NC. OrbusNeich is headquartered in Hong Kong and has operations in Shenzhen, China; Fort Lauderdale, Fla.; Hoevelaken, The Netherlands; and Tokyo, Japan. OrbusNeich supplies medical devices to interventional cardiologists in more than 60 countries. For more information, visit [www.OrbusNeich.com](http://www.OrbusNeich.com).

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