OrbusNeich Launches World's First Dual Therapy Stent That Addresses Challenges of Delayed Coronary Artery Healing Associated with Monotherapy Drug Eluting Stents

The Associated Press

OrbusNeich today launched the world's first dual therapy stent - the COMBO Dual Therapy Stent - to address the challenges of delayed healing of the coronary artery associated with monotherapy drug eluting stents (DES), the current standard of care for the treatment of coronary artery disease (CAD).

The introduction of the COMBO Stent is in conjunction with the company's receipt of a CE Mark for the product and involves a sales roll-out in Europe and selected markets in the Asia Pacific and Middle East regions.

The COMBO Dual Therapy Stent is the first stent to both accelerate endothelial coverage and control neo-intimal proliferation through the combination of OrbusNeich's proven pro-healing technology with an abluminal sirolimus drug elution delivered from a biodegradable polymer that achieves full and complete dissipation by 90 days.

"The COMBO Dual Therapy Stent is the next wave of drug eluting stent technology," said Al Novak, OrbusNeich's chairman and CEO. "The dual therapy approach maintains the efficacy of monotherapy drug eluting stents while providing the benefits of accelerated stent endothelialization and healing. At OrbusNeich, we believe that minimizing restenosis in the near term and maximizing healing in the long term are of equal importance. Interventional cardiologists now have a no-compromise solution that offers both. With CE Mark approval, the COMBO Dual Therapy Stent has set a new, rigorous standard for stent innovation." Roxana Mehran, M.D., Mount Sinai Medical Center, said, "I believe that COMBO is the next-next-generation drug eluting stent, combining the anti-restenotic property of drug eluting stents with endothelial progenitor cell (EPC) capture, which is able to heal the surface of the stent. We're most excited about the possibility of actually having a stent for which you do not need prolonged dual antiplatelet therapy (DAPT), and I think that is the future. Obligatory, prolonged DAPT is no longer going to be the standard - we cannot accept that anymore.

And so, we're looking for a safer stent, and I think this very unique and interesting platform has incredible promise." Nine-month clinical outcomes from the REMEDEE study confirmed that the COMBO Stent is as effective as a monotherapy DES, with respect to in-stent late lumen loss at nine-month angiographic follow-up (News Release, Nov. 14, 2011). These data were used to support CE Mark approval for COMBO.

"Late stent thrombosis is still a concern for patients treated with monotherapy DES, leaving them dependent on a minimum of six months DAPT," said Michael Haude, M.D., director of Medical Clinic I at the Lukaskrankenhaus in Neuss, Germany, and principal investigator of the REMEDEE trial. "We also know that cessation of DAPT is the single most significant predictor of stent thrombosis for these patients. If cessation of DAPT is necessary, the COMBO Stent may enable us to stop DAPT without causing a catastrophic event. Thus the COMBO Stent has the potential to bring the best of both worlds together, balancing safety and efficacy." The antiproliferative property of DES is known to interfere with endothelialization and, consequently, to increase the risk for stent thrombosis (ST). The addition of OrbusNeich's proprietary pro-healing antibody surface coating provides protection against ST by capturing EPCs circulating in the blood to the device to form a functional endothelial layer.

"Studies have shown that drug eluting stents adversely impact endothelial proliferation, migration and function," said Renu Virmani, M.D., of the CVPath Institute Inc. in Gaithersburg, Md. "Conversely, EPCs have the ability to migrate to areas of vascular injury and aid in the regeneration of damaged and dysfunctional endothelium. By combining drug elution with the EPC capture technology, the COMBO Stent may restore endothelial function. In addition, the COMBO Stent is the only stent with full and complete polymer degradation within 90 days, affording it the safety profile of a bare metal stent with the added benefit of allowing healing while suppressing smooth muscle cell proliferation." Stephen M. Rowland, Ph.D., vice president of research and development at OrbusNeich, said, "COMBO was designed to address the limitations of DES monotherapy associated with delayed or impaired healing. With this new technology, we have a stent that combines sustained control of smooth cell proliferation with accelerated vascular healing driven by our EPC capture technology." 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 achieves full and complete dissipation by 90 days.

OrbusNeich's patented 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 pro-healing stent, the GenousT Stent, and the world's first dual therapy stent, the COMBO Dual Therapy Stent. Other products include stents and balloons marketed under the names of AzuleT, R stent, ScoreflexT, SapphireT, 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.

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