Press Release

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BIOTRONIK releases line-extension of Orsiro Hybrid Drug Eluting Stent

The highly deliverable Orsiro stent is now available in lengths up to 40 mm to address a wider range of lesions

BERLIN, Germany, September 2, 2013—BIOTRONIK, a leading manufacturer of innovative medical technology, has announced the market release of new 35 and 40 mm versions of Orsiro, the industry's first hybrid DES (Drug Eluting Stent) featuring a bioabsorbable polymer. BIOTRONIK now offers one of the longest drug-eluting stents on the market across all diameters.

The Orsiro 40 mm was first implanted by Dr. Heinz-Joachim Büttner, MD of University Heart Center, Bad Krozingen, Germany. "The low strut thickness and good deliverability of Orsiro is even more evident in long lengths," commented Dr. Büttner "With the addition of the new sizes, there is now an Orsiro available for almost every case."

The efficacy and safety of Orsiro was recently demonstrated in two high profile studies, BIOFLOW-II and BIOFLOW-III, which showed that Orsiro performs as best in class. The robust clinical evidence of the BIOFLOW-II study was presented at the 2013 EuroPCR congress by principal investigator, Prof. Stephan Windecker, MD of University Hospital Bern, Switzerland. BIOFLOW-II is a prospective, international, multi-center, randomized trial which evaluated the safety and efficacy of Orsiro compared to Abbott's XIENCE PRIME™. At nine months, the results for the primary endpoint in-stent late lumen loss were 0.10 ±0.32 mm in the Orsiro arm and 0.11 ±0.29 mm in the XIENCE PRIME™ arm evaluated by an independent core laboratory and confirming the non-inferiority hypothesis (p-value for non-inferiority <0.0001). No significant differences were reported for the clinical end-points at nine months. Additionally no stent thrombosis was reported in either arm.

"With the addition of the 35 and 40 mm lengths, Orsiro now has a complete size range. The new lengths, in combination with the great deliverability, means that physicians can use Orsiro across a wider range of lesions," commented Alain Aimonetti, Vice President Sales and Business Development, BIOTRONIK Vascular Intervention. "The impressive results from the BIOFLOW-II and BIOFLOW-III trials demonstrate the excellent performance of Orsiro and firmly place it at the forefront of the stent market."

About Orsiro Hybrid DES
Launched in 2011, Orsiro is the industry's first Hybrid DES with a bioabsorbable polymer matrix. Orsiro is a unique solution for treating coronary artery stenosis with a hybrid combination of passive and active components. The PROBIO passive coating encapsulates the stent and minimizes interaction between the metal stent and the surrounding tissue. The active coating, BIOlute, contains a highly biocompatible polymer that delivers a limus drug via a bio-absorbable matrix. This hybrid coating is layered on top of the high performance PRO-Kinetic Energy stent platform, renowned for its advanced, thin-strut stent design and outstanding deliverability

About BIOTRONIK SE & Co. KG
As one of the world's leading manufacturers of cardiovascular medical devices, BIOTRONIK is headquartered in Berlin, Germany, and represented in over 100 countries by its global workforce of more than 5600 employees. Several million heart patients around the world have received BIOTRONIK implants, designed to save and improve the quality of their lives. Since its development of the first German pacemaker in 1963, BIOTRONIK has launched several innovations into the market—including remote monitoring with BIOTRONIK Home Monitoring® in 2000 and the world's first implantable cardioverter-defibrillators and implantable heart failure therapy devices with ProMRI® technology, approved for MR scanning, in 2012.

For more information, visit: www.biotronik.com

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