Press Release

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BIOTRONIK Japan Announces First Patients Enrolled in BIOFLOW-IV Clinical Study

BIOFLOW-IV aims to compare Orsiro Hybrid Drug-Eluting Stent to Abbott's Xience Prime/Xpedition

TOKYO, Japan, October 24, 2013 – BIOTRONIK Japan has announced enrollment of the first patient in the BIOFLOW-IV study, which aims to verify the efficacy and safety of the Orsiro Hybrid Drug-Eluting Stent (DES) from BIOTRONIK. The high quality and efficacy of Orsiro has already been confirmed by three important trials, BIOFLOW-I, -II, and –III, which demonstrated the safety and efficacy of Orsiro.

The BIOFLOW-IV study is the first prospective, randomized, controlled, global study to compare the target vessel failure (TVF) rate of Orsiro DES and Abbott's Xience Prime/Xpedition DES in a non-inferiority setting. 12 sites in Japan and 29 sites in the EU are participating in the multi-center study with the primary endpoint of TVF at 12 months.

Coordinating investigator of the BIOFLOW-IV study, Dr. Shigeru Saito, MD, Director of the Cardiology and Catheterization Laboratories and Vice President of Shonan Kamakura Hospital, Kanagawa, Japan, implanted the first stent in the study. He commented, "Orsiro has excellent deliverability and obviously thinner struts by IVUS observation than the current available DESs in Japan, which would be associated with earlier neointimal coverage after Orsiro implantation."

Efficacy and safety of Orsiro as demonstrated by the BIOFLOW-I, -II, and -III studies:

In the BIOFLOW-I first in-man study, late lumen loss, which was the primary endpoint, was 0.05±0.22mm at 9 months.

Presented at EuroPCR 2013, BIOFLOW-II was a prospective, non-inferiority randomized controlled study comparing Orsiro with Xience Prime. The primary endpoint in-stent late lumen loss at 9 months verified non-inferiority, which was confirmed with 0.10±0.32mm vs. 0.11±0.29mm, respectively. There was also no significant difference in target lesion failure (TLF) at 9 months, which was 4.8% in the Orsiro arm vs. 5.3% in the Xience arm.

The BIOFLOW-III study has also demonstrated excellent results. As a prospective, all-comers, multi-center registry, its primary endpoint demonstrated 4.7% of TLF at 12 months.

About Orsiro
Orsiro received CE mark in 2011 and features the latest development in BIOTRONIK stent technology: a unique hybrid solution that combines passive and active components. PROBIO passive coating encapsulates the stent and minimizes interaction between the metal and the surrounding tissue. BIOlute active coating contains a highly biocompatible polymer that delivers a limus drug via a bioabsorbable matrix. This hybrid coating is layered on top of the high performance PRO-Kinetic Energy bare metal stent platform, renowned for its advanced thin-strut stent design and outstanding deliverability.

About BIOTRONIK
As one of the world's leading manufacturers of cardio- and endovascular 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 patients have received BIOTRONIK implants designed to save and improve the quality of their lives, or have been treated with BIOTRONIK coronary and peripheral vascular intervention products. Since its development of the first German pacemaker in 1963, BIOTRONIK has engineered many innovations, including BIOTRONIK Home Monitoring®, the world's first 4 F-compatible 200mm peripheral stent, Orsiro, the industry's first hybrid drug-eluting stent, and the world's first implantable cardioverter-defibrillators and heart failure therapy devices with ProMRI® technology. This year BIOTRONIK celebrates its 50th anniversary.

For more information, visit: www.biotronik.com

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