Press Release

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Vascular Intervention

New Data on BIOTRONIK Orsiro Hybrid Drug-Eluting Stent Demonstrates Enhanced Safety and Three-Times Reduced Risk of Stent Thrombosis

One Year Data from Industry-Independent SORT OUT VII Trial Presented at EuroPCR 2015 Reveals Orsiro Is Non-Inferior to Nobori Stent in Large, All-Comers Population

BUELACH, Switzerland, May 26, 2015—BIOTRONIK, a leading manufacturer of cardio- and endovascular medical technology, announced that positive new data regarding Orsiro, the industry's first hybrid Drug-Eluting Stent (DES), was presented at EuroPCR 2015 in Paris, France. One year results from the SORT OUT VII trial confirmed Orsiro's non-inferiority to the bioabsorbable polymer biolimus-eluting Nobori stent in an all-comers population. Encouragingly, patients in the Orsiro arm had a significantly lower rate of definite stent thrombosis, a potentially dangerous adverse event following coronary intervention: only 0.4 percent of Orsiro patients compared with 1.2 percent of patients in the Nobori arm (p=0.03).

During a Hot Line session at EuroPCR, SORT OUT VII principal investigator Dr. Lisette Okkels Jensen, Odense University Hospital, Denmark, described the design and endpoints of the investigator-initiated randomized, multi-center, two-arm, non-inferiority study. SORT OUT VII compares the ultra-thin strut sirolimus-eluting Orsiro to the biolimus-eluting Nobori DES in the treatment of coronary artery lesions. During the trial, 1,261 patients underwent treatment with Orsiro, while 1,264 patients were treated with Nobori. At one year, the primary endpoint target lesion failure (TLF), defined as a composite of cardiac death, myocardial infarction or target lesion revascularization within one year, occurred in 3.8 percent of Orsiro patients vs. 4.6 percent of those treated with Nobori DES (p-value for non-inferiority < 0.0001).

During the Hot Line session at EuroPCR, physicians discussed potential explanations for Orsiro's enhanced safety profile and low rate of stent thrombosis. Orsiro's unique ultra-thin strut stent design enables greater flexibility than thicker strut designs, and may lead to improved apposition to the vessel wall and quicker endothelialization following percutaneous coronary intervention.

"Several factors, including significantly thinner struts and more controlled drug release, distinguish Orsiro from other bioabsorbable polymer DES," commented Dr. Jensen. "These refinements could

explain the trend towards lower rates of adverse events for Orsiro, exemplified by the considerably reduced risk of definite stent thrombosis seen in SORT OUT VII."

"These highly encouraging results reconfirm those of BIOSCIENCE, the largest independent comparison between Orsiro and Xience Prime to date. BIOSCIENCE confirmed Orsiro's performance as best-in-class and its results were published in the Lancet," stated Dr. Daniel Buehler, President, Vascular Intervention at BIOTRONIK. "Now Orsiro has once again proven itself in an even larger, real-world patient population, demonstrating superior efficacy and safety. We are certain that Orsiro's advanced ultra-thin strut design and outstanding drug deliverability will continue to impress."

About Orsiro
The Orsiro Hybrid Drug-Eluting Stent (DES), launched in 2011, 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 stent 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 stent platform, renowned for its advanced ultra-thin strut stent design and outstanding deliverability.

About BIOTRONIK
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 5,600 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.

For more information, visit: www.biotronik.com

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