Press Release

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Vascular Intervention

BIOSCIENCE Trial Further Confirms Orsiro as Best in Class

The BIOTRONIK Stent is the only Vascular Intervention Product Featured in this Year's ESC Hot Line Sessions

BARCELONA, Spain, Sept 1, 2014 – Late-breaking results of the BIOSCIENCE study were announced today in a Hot Line session at the ESC Congress by study investigator Dr. Thomas Pilgrim, University Clinic for Cardiology, Bern, Switzerland. The independent study was intended to confirm the safety and efficacy of Orsiro, the world's first Hybrid Drug-Eluting Stent. The BIOTRONIK stent represents the only vascular intervention technology to have been accepted into the elite Hot Line sessions at ESC. The announcement of Orsiro's excellent results will be accompanied by publication in the prestigious The Lancet journal, yet more evidence that this highly innovative product is truly best in class.

BIOSCIENCE is an investigator initiated, multi-center, randomized, controlled, all-comers non-inferiority study. It is the largest published industry-independent comparison to date evaluating the safety and efficacy of a sirolimus-eluting stent with a biodegradable polymer and an everolimus-eluting stent with a durable polymer. For the study, each device was used in the treatment of patients undergoing percutaneous coronary intervention in routine clinical practice. BIOSCIENCE confirms and builds on results from several clinical trials demonstrating the excellence of Orsiro, including the recent BIOFLOW-II trial, which demonstrated the safety and efficacy of Orsiro against Abbott's Xience Prime. BIOSCIENCE compares these two products once again, but this time with a primary clinical endpoint in a much larger population of 2119 patients.

"The results of the BIOSCIENCE trial show that in a large patient population reflecting routine clinical practice, Orsiro, with its ultra-thin strut, is as safe and efficacious as the thin-strut Xience Prime," commented Dr. Pilgrim during his presentation. "'The observed benefit in the pre-specified subgroup with ST-segment elevation myocardial infarction warrants further study."

The primary endpoint of the study was Target Lesion Failure (TLF), defined as a composite of cardiac death, target vessel Q-wave or non-Q-wave myocardial infarction (MI) and clinically driven Target Lesion Revascularization (TLR) at 12 months. Encouragingly, primary

endpoint results from the 12-month follow-up demonstrated that Orsiro met its study objective of non-inferiority versus Xience Prime, hence performing as best in class.

"We are particularly proud to see Orsiro doing so well in an all-comers trial with a large, real-world patient population and a clinical endpoint," commented Dr. Daniel Bühler, President Vascular Intervention at BIOTRONIK. "Our aim is to provide physicians with the most innovative, reliable tools available. The results of BIOSCIENCE show that Orsiro is a Masterpiece—one that physicians can rely on when giving patients the very best treatment."

12-month TLF results of the BIOSCIENCE study at a glance

	Orsiro Hybrid DES	**Xience Prime**	***p-values***
Target Lesion Failure (TLF)	**6.5%**	**6.6%**	p-value for non-inferiority <0.001
Cardiac death	1.9%	2.1%	No statistically significant difference
Target vessel Q-wave or non-Q wave MI	2.9%	3.0%	No statistically significant difference
Clinically driven TLR: percutaneous, surgical	3.4%	2.4%	No statistically significant difference

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 system is layered on top of the high performance PRO-Kinetic Energy stent platform, renowned for its advanced thin-strut stent design and exceptional 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 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.

For more information, visit: www.biotronik.com

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