Press Release

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Page: 1/2

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Vascular Intervention

EuroPCR 2016: Magmaris*, the First Clinically Proven Bioresorbable Magnesium Scaffold, Shows Long-Term Safety in BIOSOLVE-II Trial

12 Month Results Demonstrate No Incidence of Scaffold Thrombosis and Low Rate of Target Lesion Failure

PARIS, France and BUELACH, Switzerland, May 17, 2016 – BIOTRONIK today presented 12 month data from the BIOSOLVE-II trial during a Hotline Session at EuroPCR 2016. The study established the safety and clinical performance of Magmaris*, the world's first clinically proven magnesium-based sirolimus eluting bioresorbable scaffold. Full one year data from the prospective, international first-in-human trial has been published in *The European Heart Journal* concurrently with the Hotline Session.

"These results offer the first confirmation of Magmaris's* longer-term safety and efficacy," stated BIOSOLVE-II principal investigator Dr. Michael Haude of the Lukaskrankenhaus, Neuss, Germany. "BIOSOLVE-II demonstrates a promising potential of a magnesium-based approach to treating coronary artery disease as an alternative to polymer-based bioresorbable scaffolds."

BIOSOLVE-II is the first trial to evaluate the safety and clinical performance of Magmaris*. 123 patients with *de novo* lesions were enrolled in Germany, Belgium, Denmark, the Netherlands, Switzerland, Spain, Brazil and Singapore. The trial's primary endpoint was in-segment late lumen loss (LLL) at six months, with an LLL of 0.27 ± 0.37 mm observed at six months. The voluntary 12 month follow-up now reports an LLL of 0.25 ± 0.22 mm. Magmaris* had previously met its primary angiographic endpoint and demonstrated an outstanding safety profile at six months; the results were published in *The Lancet.*

Particularly encouraging from the perspective of device safety was the total absence of stent thrombosis at 12 months. Furthermore, a low rate of target lesion failure (TLF) of 3.4 percent was observed at six months, with no additional TLF occurring between six and 12 months.

"BIOSOLVE-II has paved the way for a novel magnesium bioresorbable scaffold which offers outstanding deliverability without leaving an implant behind," commented Dr. Daniel Buehler, BIOTRONIK President, Vascular Intervention. "The current clinical evidence will be augmented with a robust post-market clinical program, including the BIOSOLVE-IV trial."

About Magmaris*
Magmaris* is a sirolimus-eluting bioresorbable magnesium scaffold exclusively available from BIOTRONIK. Due to the scaffold's magnesium backbone, it offers novel benefits that only a metallic scaffold can offer such as desired deliverability, strong radial support and a fast resorption time of approximately 12 months. In addition, the proven BIOlute coating consisting of a sirolimus drug and an excipient ensures a controlled drug release to control cell growth similar to Orsiro, BIOTRONIK's hybrid drug-eluting stent.

* CE mark pending

About BIOTRONIK
A global leader in cardio- and endovascular medical technology, BIOTRONIK is headquartered in Berlin, Germany, and represented in over 100 countries. 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®; Pulsar, the world's first 4 F compatible stent for treating long lesions; 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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