# Press Release

Date: October 13, 2015

Page: 1/2

Woermannkehre 1
12359 Berlin
Tel +49 30 68905-1414
Fax +49 30 68905-961414
www.biotronik.com

**Vascular Intervention**

## BIOSOLVE-II Trial Establishes Safety and Clinical Performance of World's First Clinically Proven Magnesium Bioresorbable Scaffold

### BIOTRONIK Magnesium Scaffold Demonstrates Exceptional Safety, with No Scaffold Thrombosis at Six Months

- BIOTRONIK Magnesium Scaffold met its primary angiographic endpoint
- Magnesium-based properties promote a faster and simpler implantation procedure
- Can be inflated in a single step
- Absorbed within 12 months, faster than polymer-based bioresorbable scaffolds

SAN FRANCISCO, US and BUELACH, Switzerland, October 13, 2015 – BIOTRONIK, a leading manufacturer of cardio- and endovascular medical technology, has announced results from the BIOSOLVE-II trial investigating the safety and clinical performance of the world's first clinically proven magnesium-based bioresorbable scaffold at TCT 2015. The bioresorbable scaffold met its primary angiographic endpoint and demonstrated an outstanding safety profile. The announcement of clinical data from BIOSOLVE-II will be accompanied by publication in the prestigious journal *The Lancet*, further evidence of the quality of these results.

"The results of BIOSOLVE-II confirm that the BIOTRONIK Magnesium Scaffold is both a safe and effective option for treating coronary artery disease (CAD), and establish it as the first clinically-proven magnesium-based bioresorbable scaffold," commented principal investigator of the study Dr. Michael Haude of the Lukaskrankenhaus, Neuss, Germany. "The device's favorable safety profile, as demonstrated by the lack of any scaffold thrombosis (ST) at six months from implantation, was especially remarkable."

BIOSOLVE-II is a prospective, multi-center, first-in-man trial evaluating the safety and clinical performance of the BIOTRONIK Magnesium Scaffold; 123 patients 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; a LLL of 0.27 ± 0.37 mm was associated with the device. Additionally, a low rate of target lesion failure (3.3%) and a very low rate of myocardial infarction (0.8%) were observed.

The results of BIOSOLVE-II will be used to obtain CE approval for the device.

"The BIOTRONIK Magnesium Scaffold shows advantages over synthetic polymer-based scaffolds as it can be inflated in a single step. It is based on a natural element widely present in the human body, and the magnesium-based properties promote a faster and simpler implantation procedure," commented Dr. Haude. "Additionally, the magnesium is absorbed within 12 months, faster than polymer-based bioresorbable scaffolds, while vasomotion is observed at 6 months. I look forward to this device attaining CE mark, so I can use it in my patients also outside of trials."

"As a global pioneer in magnesium technology in the cardiovascular field, we pride ourselves on being the first company to gain clinical evidence supporting the safety and clinical performance of our magnesium-based scaffold with this ground-breaking trial," commented Dr. Daniel Buehler, BIOTRONIK President, Vascular Intervention. "These highly promising results further establish BIOTRONIK as an innovator, and open a new chapter in the field of vascular intervention."

**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 200 mm 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

**Contact:**
Manuela Schildwächter
Senior Manager Communications & PR
BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin, Germany
Tel. +49 30 68905-1414
Email: press@biotronik.com