



## News

### UK's First Heart Patient Treated with Abbott's Groundbreaking Bioresorbable Vascular Scaffold

*UK to Play Key Role in ABSORB EXTEND, A Global Trial Studying Revolutionary "Disappearing" Heart Device*

M Maidenhead, UK, 28 September 2010 — Abbott today announced the enrolment of the first UK heart patient in a trial to further evaluate the performance of the company's bioresorbable vascular scaffold (BVS). BVS is a revolutionary technology - the first drug-eluting implant of its kind designed to open up a narrowed artery without leaving a permanent metal implant behind in the blood vessel.

Abbott's BVS is designed to restore blood flow by opening a narrowed artery and providing support while the opened area heals. Once the device is no longer required, the bioresorbable scaffold is designed to slowly dissolve and eventually be resorbed by the body. Since with this technology a permanent metal implant is not left behind, a vessel treated with a BVS may return to normal functioning. This potential restoration of function makes Abbott's BVS unique in the treatment of coronary artery disease.

The first UK patient was enrolled into the ABSORB EXTEND clinical trial at University Hospitals of Leicester, by Professor Anthony Gershlick, Consultant Cardiologist. He thought this was potentially a very important advance in the management of patients with coronary artery disease. "There have been a number of revolutionary advances in the management of coronary artery disease in the past 30 years, but it has been suggested through research that a more elegant approach might be to design the stent itself to be slowly metabolised leaving nothing behind, allowing the artery to be more functionally normal," said Professor Gershlick of University Hospitals of Leicester.

"Abbott's BVS technology appears to combine scaffolding and drug release for the artery with a planned resorption of the device over a period of about two years. Thus the narrowing can be treated, with resolution of the patients symptoms through the use of the drug released and yet the device is resorbed. While it is early days, the bioresorbable vascular scaffold may be the next quantum leap in how interventional cardiologists treat symptomatic coronary artery disease."

Abbott's BVS, which is under clinical investigation in Europe, Australia and New Zealand and is not currently commercially available, is made of polylactide, a proven biocompatible material that is commonly used in medical implants such as dissolvable sutures.

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"The ABSORB EXTEND trial reinforces Abbott's commitment to research and develop innovative devices for vascular care," said Sue Hudson, General Manager, Abbott Vascular, UK." The BVS promises to be an important next step in the treatment of coronary artery disease, and Abbott is committed to making this revolutionary technology a clinical reality."

Abbott is the only company with long-term clinical data evaluating the safety and performance of a fully bioresorbable drug-eluting vascular scaffold. Results from the first stage of the ABSORB trial with 30 patients demonstrated that Abbott's BVS successfully treated coronary artery disease and was resorbed into the walls of the treated arteries. Patients in this first phase of the ABSORB trial experienced no stent thrombosis (blood clots) out to three years and no new major adverse cardiac events (MACE<sup>1</sup>). The treated vessels were able to expand and contract without being restricted by a permanent metal implant – indicating that the device was resorbed.

**About the ABSORB EXTEND Clinical Trial**

The UK will be contributing to the larger ABSORB EXTEND single-arm trial that will enrol approximately 1,000 patients from up to 100 centres in Europe, Asia Pacific, Canada and Latin America.

The ABSORB EXTEND trial will enrol patients with more complex coronary artery disease and will provide data that will be used to support approval in various markets around the world. Key endpoints of the study include – MACE and treated site thrombosis rates – at 30 days; six, 12, 24 and 36 months, as well as an assessment of the acute performance of the bioresorbable vascular scaffold, including successful deployment of the system. Other key endpoints of the study include imaging assessments by angiography, intravascular ultrasound (IVUS), optical coherence tomography (OCT), and other state-of-the-art invasive and non-invasive imaging modalities.

Everolimus is developed by Novartis Pharma AG and is licensed to Abbott by Novartis for use on its drug eluting vascular devices. Everolimus has been shown to inhibit treated site neointimal growth in the coronary vessels following vascular device implantation, due to its anti-proliferative properties.

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<sup>1</sup>MACE is a composite measure of key efficacy and safety endpoints and includes cardiac death, heart attack (myocardial infarction) and ischemia-driven target lesion revascularisation.

**About Abbott Vascular**

Abbott Vascular is a global leader in cardiac and vascular care with market leading products and an industry-leading pipeline. Abbott Vascular offers a comprehensive cardiac and vascular devices portfolio, including products for coronary artery disease, vessel closure, endovascular disease, and structural heart disease.

**About Abbott**

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs approximately 83,000 people and markets its products in more than 130 countries.

Abbott's news releases and other information are available on the company's Web site at [www.abbott.com](http://www.abbott.com).

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