Abbott Initiates Clinical Trial of AbsorbT in the United States

The Associated Press

Abbott (NYSE: ABT) announced today the initiation of the ABSORB III clinical trial in patients in the United States. This randomized, controlled trial is designed to enroll approximately 2,250 patients, the majority in the United States, and compare the performance of Abbott's drug eluting AbsorbT Bioresorbable Vascular Scaffold (BVS) device to the company's XIENCET family of drug eluting stents. The start of this trial in the United States follows the recent international commercial launch of Absorb in Europe and parts of Latin America and Asia, including the recent regulatory approval and launch in India - a country with a significant and growing prevalence of heart disease. Data from the ABSORB III trial will support U.S. regulatory filings for Absorb.

Absorb, a drug eluting, fully bioresorbable vascular scaffold1, is an innovative device for the treatment of coronary artery disease, which is a narrowing of one or more arteries that supply blood to the heart.

Absorb is made of polylactide, a naturally dissolvable material that is commonly used in medical implants such as dissolving sutures.

Absorb works by opening a clogged vessel and restoring blood flow to the heart similar to a drug eluting metallic stent, the current standard of care. Absorb then dissolves into the blood vessel, leaving behind a treated vessel that may resume more natural function and movement because it is free of a permanent metallic implant.1,2 Dean Kereiakes, M.D., FACC, FSCAI, medical director of The Christ Hospital Heart & Vascular Center and the Lindner Research Center in Cincinnati, and professor of clinical medicine at Ohio State University, was one of the first physicians to enroll a patient into the ABSORB III trial. "The deliverability of the Absorb device is impressive and similar to a best-in-class drug eluting stent," said Dr. Kereiakes, who is a co-primary investigator of the ABSORB III trial. "Absorb combines the unique attributes of a dissolvable material with the established MULTI-LINK stent design, making the scaffold flexible and conformable to the vessel." The ABSORB III clinical trial is designed to evaluate potential benefits of Absorb in patients with coronary artery disease. Unlike a permanent metallic stent, preliminary evidence of natural vessel function suggests that treatment with an Absorb BVS could provide important clinical benefits.

"With the introduction of balloon angioplasty in the 1970s, cardiologists wanted to open a blocked vessel without leaving anything behind. Absorb represents the latest innovation that may help us reach this goal, which could result in important long-term benefits related to the restoration of natural vessel function," said Stephen Ellis, M.D., section head of Interventional Cardiology at the Cleveland Clinic and co-primary investigator of the ABSORB III trial. "The data collected on Absorb

from the ABSORB III trial could have the potential to drive significant changes in how cardiologists treat patients with coronary artery disease." The primary endpoint of ABSORB III is target lesion failure, a combined measure of safety and efficacy, at one year. In addition, a subset of patients within the trial will be evaluated for novel endpoints such as vasomotion, a measure of how much natural motion returns to the vessel as Absorb dissolves into the arterial tissue.

"Absorb is an excellent demonstration of Abbott's continued global leadership and innovation. The ABSORB III trial will provide important insight about the benefits of Absorb in U.S. patients with heart disease and will supplement the knowledge gained about this technology since the start of international clinical trials of Absorb in 2006," said Charles A. Simonton, M.D., FACC, FSCAI, divisional vice president, Medical Affairs, and chief medical officer, Abbott Vascular. "The advancement of Absorb into clinical trials in the United States represents an important step in the process of filing for U.S. regulatory approval - with the goal of establishing Absorb as a new therapeutic option to treat U.S. patients with heart disease, the number one killer of men and women." About the Absorb Bioresorbable Vascular Scaffold The Absorb Bioresorbable Vascular Scaffold, similar to a small mesh tube, is designed to open a blocked heart vessel and restore blood flow to the heart. Absorb is referred to as a scaffold to indicate that it is a temporary structure, unlike a metallic stent, which is a permanent implant. The scaffold provides support to the vessel until the artery can stay open on its own, and then dissolves naturally over time.

Absorb leaves patients with a vessel free of a permanent metallic implant and may allow the vessel to resume more natural function and movement, potentially providing long-term benefits.1,2 Abbott's BVS delivers everolimus, an anti-proliferative drug used in Abbott's XIENCE coronary stent systems. Everolimus was 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 in-stent neointimal growth in the coronary vessels following stent or scaffold implantation.

Approximately 1,000 patients from more than 20 countries have been treated with the Absorb BVS device across multiple clinical trials, with data out to five years on the first patients treated.

Absorb is an investigational device, limited by United States law to investigational use and is not approved or available for sale in the United States. Absorb is authorized for sale in CE Mark countries.

Absorb is available in Europe, the Middle East, parts of Latin America, and parts of Asia Pacific, including India, Hong Kong, Malaysia and New Zealand.

The MULTI-LINK stent design includes MULTI-LINK VISION@, XIENCE V@, XIENCE PRIME@ and, most recently, XIENCE XpeditionT. More than 11 million implants of the MULTI-LINK platform have occurred worldwide.

About Abbott Vascular Abbott Vascular is the world's leader in drug eluting stents. Abbott Vascular has an industry-leading pipeline and a comprehensive portfolio of

market-leading products for cardiac and vascular care, including products for coronary artery disease, vessel closure, endovascular disease and structural heart disease.

About Abbott Abbott is a global healthcare company devoted to improving life through the development of products and technologies that span the breadth of healthcare. With a portfolio of leading, science-based offerings in diagnostics, medical devices, nutritionals and branded generic pharmaceuticals, Abbott serves people in more than 150 countries and employs approximately 70,000 people.

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1Absorb completely dissolves except for two pairs of tiny metallic markers, which help guide placement and remain in the artery to enable a physician to see where the device was placed.

2Preliminary evidence suggests that natural vessel function is possible and may improve long term outcomes. Absorb is a trademark of the Abbott Group of Companies.

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