ABBOTT INITIATES ABSORB IV TRIAL TO EVALUATE QUALITY OF LIFE AND COST SAVINGS OF DISSOLVING HEART DEVICE

- Abbott's Absorb Bioresorbable Vascular Scaffold (BVS) is a revolutionary medical device used in the heart that functions like a stent but dissolves over time

- ABSORB IV will compare Absorb to a best-in-class, metallic drug eluting stent in people with coronary artery disease, the most common type of heart disease

- Trial will prospectively measure rates of angina, or chest pain, in the first randomized controlled heart stent trial with angina as a primary endpoint to assess impact of angina on healthcare costs and quality of life

ABBOTT PARK, Ill., Sept. 15, 2014 /PRNewswire/ -- Abbott announced today the start of the ABSORB IV clinical trial, which will test whether its Absorb Bioresorbable Vascular Scaffold (BVS) is more cost-effective and offers a higher quality of life than a best-in-class, permanent, metallic drug eluting stent. Absorb is the world's first drug eluting BVS and functions like a metallic stent by opening up blocked blood vessels in the heart and restoring blood flow. However, unlike a metallic stent, Absorb completely dissolves over time after doing its job. ABSORB IV is designed to enroll approximately 3,000 people with coronary artery disease, mostly in the United States.

ABSORB IV is the first randomized heart stent trial to prospectively measure angina as a primary endpoint at one year. Angina is commonly described as chest pain and is caused by reduced flow of oxygen-rich blood to the heart. Measuring angina is significant because of its impact on quality of life and healthcare costs.[1,2] Overall, people who have angina following a percutaneous coronary intervention (PCI) use more healthcare resources than those without angina.[3] Studies have shown that while PCI with metallic stents is highly effective, by reducing angina for 75 percent of treated patients, about 25 percent of people treated still experience angina over the course of the year following PCI. In addition, people with frequent angina typically have a lower quality of life because they are less likely to lead active lifestyles than those without angina.[4]

Randomized data recently presented from the ABSORB II clinical trial, conducted primarily in Europe, showed that people treated with Absorb experienced significantly less angina compared to those who received a permanent metallic stent. The ABSORB IV trial is designed to confirm these novel findings that treatment with the Absorb device can help provide people with heart disease a higher quality of life after a heart stent procedure.

The other primary endpoint of ABSORB IV assesses long-term clinical safety and performance based on the change in target lesion failure (TLF) from one to five years. TLF is a traditional endpoint in heart stent trials used to measure the safety and effectiveness of a device. Data from the ABSORB II clinical trial showed a similar rate of TLF between Absorb and XIENCE at one year. ABSORB IV is designed to demonstrate that this performance is consistent out to five years in people treated in the U.S.

"The ABSORB IV trial will rigorously and prospectively examine whether there are differences in angina rates between a permanent stent and a dissolvable device after a percutaneous coronary intervention," said Gregg Stone, M.D., FACC, FSCAI, director, cardiovascular research and education, Center for Interventional Vascular Therapy, Columbia University Medical Center, New York-Presbyterian Hospital and principal investigator of the ABSORB IV trial. "People care about their quality of life following a procedure, and this trial will allow us to measure that important outcome, in addition to traditional clinical endpoints."

Absorb is made of polylactide, a naturally dissolvable material that is commonly used in medical implants, such as dissolving sutures. Absorb is called a scaffold to indicate its temporary structure, and the scaffold provides support to the vessel until the artery can stay open on its own. Absorb slowly dissolves into the blood vessel, leaving behind a vessel that has the potential to resume more natural function and movement because it is not restricted by a permanent metallic stent.[5]

In ABSORB IV, people will be randomly assigned to receive either Absorb or a best-in-class, drug eluting permanent metallic stent, representing today's standard of care. The trial will implement rigorous measures to minimize patient bias and a patient perception effect. The first hospital to enroll people into the trial is The Christ Hospital Heart and Vascular Center and The Lindner Research Center in Cincinnati, Ohio.

"The ABSORB IV trial is an important step forward in determining the relative clinical benefits associated with the dissolvable device compared with the permanent metal stent," said Dean Kereiakes, M.D., FACC, FSCAI, medical director, The Christ Hospital Heart and Vascular Center and The Lindner Research Center, and national co-principal investigator of the ABSORB IV trial. "Metal stents have been an important therapy for coronary artery disease for almost 25 years, but may have limitations. ABSORB IV is designed to demonstrate differences in clinical outcomes, angina symptoms and quality of life between stent types."

The data from the ABSORB IV trial will be combined with the data from the ABSORB III trial to create a population of more than 5,000 people studied in the U.S. This data set, which is the largest of its kind for bioresorbable heart devices, provides an opportunity to rigorously evaluate the performance of Absorb

compared to the current standard of a metallic drug eluting stent across a number of measures, including the broader health economic impact of this innovative therapy.

"ABSORB IV is a new approach to heart stent trials and the first time angina as a quality of life measure has been included as a co-primary endpoint," said Charles A. Simonton, M.D., FACC, FSCAI, divisional vice president, Medical Affairs, and chief medical officer, Abbott Vascular. "The current standard of care for narrowed coronary vessels offers strong clinical outcomes for most people. However, people continue to suffer from debilitating chest pain after their procedures, which lowers their quality of life and increases associated healthcare costs. By focusing on the patients and how they feel after a procedure, this trial sets a new bar for how we measure health outcomes and how we treat people with coronary artery disease."

About Coronary Artery Disease
Heart disease is the leading cause of death for men and women around the world, and coronary artery disease is the most common type of heart disease.[6,7] Coronary artery disease occurs when arteries that supply blood to the heart become narrowed or blocked due to plaque buildup, leading to chest pain or shortness of breath and increased risk of heart attack.

About the Absorb Bioresorbable Vascular Scaffold
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.

Abbott announced CE Mark in Europe for Absorb in 2011, and the device is now available in more than 60 countries worldwide. The company recently completed enrollment in clinical trials to support approvals for Absorb in Japan and China. Combined, the U.S., Japan and China represent more than 50 percent of the world's heart stent procedures. 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.

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 (NYSE: ABT) 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 69,000 people.

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[1] Javitz HS, Ward MM, Watson JB, et al. Cost of illness of chronic angina. Am J Manag Care. 2004; 10:S358-69.

[2] Kempf J, Buysman E, Brixner D. Health Resource Utilization and Direct Costs Associated with Angina for Patients with Coronary Artery Disease in a US Managed Care Setting. Am Health Drug Benefits. 2011;4(6):353-361. www.AHDBonline.com

[3] Hlatky MA, Boothroyd DB, Melsop KA, et al. Medical Costs and Quality of Life 10 to 12 Years After Randomization to Angioplasty or Bypass Surgery for Multivessel Coronary Artery Disease. Circulation. 2004; 110: 1960-1966.

[4] Kohn et al. Impact of angina frequency on health utility values of patients with chronic stable angina. Health and Quality of Life Outcomes. 2014; 12:39.

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

[6] The top 10 causes of death, World Health Organization. June 2011
Available at: http://www.who.int/mediacentre/factsheets/fs310/en/index.html

[7] Coronary Artery Disease. National Heart, Lung and Blood Institute. May 2011
Available at: http://www.nhlbi.nih.gov/health/health-topics/topics/cad/

SOURCE Abbott

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