ABSORB II Study Shows Abbott's Dissolving Heart Device Comparable To The World's Leading Heart Stent

- 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

- One-year results show Absorb provides comparable results across several measures and lower rates of angina (chest pain) than a best-in-class drug eluting stent (DES)

WASHINGTON, Sept. 14, 2014 /PRNewswire/ -- Abbott announced today positive one-year clinical results from ABSORB II, the world's first prospective, randomized, controlled trial comparing the safety and effectiveness of the dissolving Absorb heart device to Abbott's market-leading metallic XIENCE family of DES. The trial, conducted primarily in Europe, included 501 people with coronary artery disease (CAD), the most common form of heart disease. The results were featured at a late-breaking session at the 26th Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation, in Washington D.C.

At one year, overall clinical outcomes for Absorb were comparable to XIENCE, and people treated with Absorb experienced a significantly lower rate of angina (chest pain), a novel finding given the impact of angina on people's quality of life and its cost burden on healthcare systems. Absorb is a first-of-its-kind device that functions like a metallic stent by opening a blocked artery in the heart and restoring blood flow. However, unlike a metallic stent, which cages the vessel, Absorb is more flexible and dissolves over time, leaving behind a treated vessel free of a permanent implant with the potential to flex, pulse and dilate in response to various demands on the heart, based on people's lifestyle and activities, such as exercise.[1,2]

"The results of ABSORB II provide international doctors with additional confidence to use Absorb to treat their patients based on randomized clinical data showing that Absorb provides comparable results at one year to a best-in-class metallic drug eluting stent in traditional endpoints," said Patrick W. Serruys, M.D., Ph.D., professor of interventional cardiology at the Thoraxcentre, Erasmus University Hospital, Rotterdam, the Netherlands, and principal investigator of the ABSORB II trial. "Additionally, the lower rate of chest pain observed in people treated with Absorb is a promising finding that shows that Absorb may offer people unique quality of life benefits beyond the excellent clinical outcomes already offered with drug eluting stents."

At one year, the patient-oriented clinical endpoint of all death, all heart attacks and all revascularization was 7.3 percent for Absorb and 9.1 percent for XIENCE (p=0.47). The device-oriented clinical endpoint of target lesion failure (TLF) was 4.8 percent for Absorb and 3.0 percent for XIENCE (p=0.35) at one year. The individual components of these composite endpoints were also comparable between the two treatment groups. The rates of stent thrombosis (ST) observed for Absorb at one year were low at 0.6 percent for definite ST and 0.9 percent for definite/probable ST.

The data also showed that during the course of one year, people treated with Absorb were less likely to experience angina once they left the hospital than those treated with XIENCE, at a rate of 16.4 percent versus 25.6 percent (p=0.01), respectively.[3] Angina occurs when there isn't enough oxygen-rich blood flowing to the heart muscle. Angina has a significant impact on quality of life and healthcare costs.[4] Overall, people who have angina following a heart stent procedure use more healthcare resources, including additional diagnostic and treatment tools to try to identify the source of angina, than those without angina. In addition, they typically have a lower quality of life because they are less likely to lead active lifestyles than those people without angina.[5,6,7] Therefore, reducing the burden of angina could help people live healthier lives and reduce costs to the healthcare system.

The primary endpoint of the ABSORB II trial is vessel motion at three years, at which time Absorb has fully dissolved. Without a permanent stent caging the vessel, the vessel has the potential to return to a more natural state. Clinical endpoints and quality of life measures will be assessed annually for up to three years. Imaging endpoints, or specialized pictures inside the blood vessel, will be assessed at three years.

"The excitement about a heart device that dissolves after doing its job will continue to increase with these positive results from a randomized, controlled trial showing comparable outcomes between Absorb and XIENCE," said Charles A. Simonton, M.D., FACC, FSCAI, divisional vice president, Medical Affairs, and chief medical officer, Abbott Vascular. "These data represent a significant milestone for Absorb and show how this unique technology can potentially benefit people with heart disease."

At TCT this year, data from approximately 1,500 people treated with Absorb in single-arm trials will also be released publicly for the first time. These data add to the positive results seen in the ABSORB II randomized trial by demonstrating excellent results, including in real-world settings, and strong clinical outcomes in a subgroup of people out to three years. In addition, specialized images from inside the blood vessel five years following treatment with Absorb will be presented. These data provide interesting evidence of how natural a vessel can look after Absorb completely dissolves and that vessel motion can return, reinforcing the tremendous innovation this technology offers for people with heart disease.

About the Absorb Bioresorbable Vascular Scaffold

Absorb is a first-of-its-kind device that functions like a stent by opening a blocked artery in the heart and restoring blood flow. However, after doing its job, Absorb dissolves into the vessel wall, unlike a metallic stent, which permanently cages the vessel. 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.[1,2]

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 the world's first drug eluting bioresorbable vascular scaffold to become commercially available in international markets. Abbott announced CE Mark in Europe in January 2011, and the product is now available in more than 60 countries worldwide and has been used to treat approximately 60,000 people.

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.

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] Absorb 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.

[2] Preliminary evidence suggests that natural vessel function is possible with Absorb and may improve long term outcomes.

[3] Data excludes angina episodes that occurred during hospital stay or in the 7 days after the procedure if the patient was still in the hospital at that time

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

[5] 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

[6] 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.

[7] 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.

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For further information: Media: Steve Kelly, (408) 845-3427; Gayathri Badrinath, (408) 845-8292; Financial: Tina Ventura, (224) 668-7606