Abbott Announces Positive Clinical Results Of Absorb™, The Naturally Dissolving Heart Stent

- ABSORB III pivotal trial, designed to support regulatory approval in the U.S., meets primary endpoint; ABSORB China pivotal trial meets primary endpoint

- Latest data show that Absorb performs as well as the market-leading, metallic drug eluting stent

- More than 125,000 people worldwide have been treated with Absorb™(1)

SAN FRANCISCO, Oct. 12, 2015 /PRNewswire/ -- Abbott (NYSE: ABT) announced today positive one-year clinical results from the ABSORB III trial, which compared the safety and effectiveness of Abbott's fully dissolving Absorb™ heart stent to XIENCE ®, Abbott's market-leading, metallic drug eluting stent. The trial was conducted at 193 sites, primarily in the United States, and enrolled about 2,000 people with coronary artery disease, the most common type of heart disease. The results, which showed that ABSORB III met its primary endpoint and will be used to support regulatory approval of Absorb in the U.S., were featured today during a late-breaking session at the 27th Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation. In addition, the study results were published simultaneously in The New England Journal of Medicine.

Absorb is a first-of-its-kind device that functions like a permanent, metallic stent by opening a blocked artery in the heart, restoring blood flow and providing relief from symptoms of coronary artery disease (CAD). However, unlike a metallic stent, which permanently restricts vessel movement and limits future treatment options, Absorb is made of a naturally dissolvable material that leaves behind a restored vessel in a natural state, free of a permanent implant. An unrestricted vessel with restored vessel function has the potential to flex, pulse and dilate in response to various demands on the heart, based on people's lifestyle and activities, and allows for potential future treatment options.(2,3)

"The ABSORB III data shows that there are no statistically significant one-year differences between Absorb and XIENCE, which is a major accomplishment given XIENCE's strong performance as the current standard of care," said Dean Kereiakes, M.D., FACC, FSCAI, medical director of The Christ Hospital Heart and Vascular Center and the Lindner Research Center in Cincinnati, professor of clinical medicine at Ohio State University, and a principal investigator of ABSORB III. "Naturally dissolving heart stents are the next revolution in percutaneous coronary intervention, and Absorb is leading the way as an innovative option. Absorb does its job and then restores the vessel to its natural state over time, which cannot be achieved with a permanent drug eluting stent."

Key findings of ABSORB III, a prospective, randomized, single-blinded, controlled trial, are as follows:

- A primary endpoint of target lesion failure (TLF) of 7.8 percent for Absorb and 6.1 percent for XIENCE (non-inferiority $p<0.007$, no statistically significant difference), demonstrating that both devices are comparable in treating people with CAD. TLF is a composite of heart disease-related deaths, heart attacks attributed to the treated vessel, and repeat procedures within the treated lesion caused by ischemia (lack of oxygen in the treated vessel).
- All pre-specified secondary endpoint results were not statistically different.
- There was no statistically significant difference in the rate of definite and/or probable stent thrombosis (ST).

At this year's TCT, Abbott also presented positive one-year results from ABSORB China, a prospective, randomized, single-blinded, controlled trial that compared Absorb to XIENCE to support Absorb approval in China. The trial met its non-inferiority primary endpoint of in-segment late loss at one year, with Absorb at 0.19±0.38 mm and XIENCE at 0.13 ±0.38 mm (p non-inferiority=0.01). The trial enrolled 480 people at 24 sites throughout mainland China. The results were published simultaneously in the Journal of the American College of Cardiology. During TCT Abbott will present additional data from the Absorb family of trials, which have collectively involved more than 13,000 people.

"Results of the ABSORB III pivotal trial show that Absorb is comparable to the best-in-class metallic stent. However, because Absorb leaves nothing behind it may provide significant long-term benefits, such as a restored vessel in a natural state and renewed possibilities for people treated with Absorb," said Charles Simonton, M.D., FACC, FSCAI, chief medical officer and divisional vice president, Medical Affairs, vascular, Abbott. "At Abbott we will continue to study Absorb in our robust clinical trials to show the long-term benefits of Absorb that differentiate it from permanent, metallic stents."

Absorb is available in more than 100 countries worldwide and has been used to treat more than 125,000 people. Abbott completed its submission for regulatory approval of Absorb in the United States, and it plans to submit for regulatory approval in China. ABSORB III is designed to support regulatory approval of Absorb in the United States, and ABSORB China is designed to support regulatory approval of Absorb in China. Currently, Absorb is an investigational device in the United States and China, and it is not approved for commercial use in these countries.

About the Absorb Bioresorbable Vascular Scaffold (BVS)

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 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.(4,5) 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 Abbott

At Abbott, we're committed to helping people live their best possible lives through the power of health. For more than 125 years, we've brought new products and technologies to the world -- in nutrition, diagnostics, medical devices and branded generic pharmaceuticals -- that create more possibilities for more people at all stages of life. Today, 73,000 of us are working to help people live not just longer, but better, in the more than 150 countries we serve.

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(1) Based on worldwide device utilization rate. Data on file at Abbott Vascular as of April 2015.
(2) 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.
(3) Preliminary evidence suggests that natural vessel function is possible and preserves the vessel for future interventions.
(4) The top 10 causes of death, World Health Organization. June 2011
Available at: http://www.who.int/mediacentre/factsheets/fs310/en/index.html
(5) Coronary Artery Disease. National Heart, Lung and Blood Institute. May 2011
Available at: http://www.nhlbi.nih.gov/health/health-topics/topics/cad/

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For further information: Abbott Media, Steve Kelly, (408) 845-3427, or Mira Jang, (408) 250-5782; Abbott Financial, Scott Leinenweber, (224) 668-0791

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