ABBOTT INITIATES GROUNDBREAKING STUDY TO ASSESS SUPERIORITY OF HIGH-RESOLUTION IMAGING VERSUS STANDARD-OF-CARE ANGIOGRAPHY IN TREATING CORONARY ARTERY DISEASE

- Largest-ever randomized trial to evaluate superiority of light-based, three-dimensional imaging (optical coherence tomography (OCT)) versus X-ray-based angiography in patients with complex coronary artery disease who receive a stent

- Trial will assess if stent procedures guided by high-resolution imaging result in larger vessel diameters and improved patient clinical outcomes versus stent procedures that use standard-of-care imaging

- Use of OCT imaging may help doctors be more precise in stent implantation

ABBOTT PARK, Ill., April 11, 2018 /PRNewswire/ -- Abbott (NYSE: ABT) today announced the initiation of a clinical trial evaluating long-term outcomes of patients who undergo stent implantation guided by high-resolution light-based imaging technology—called optical coherence tomography (OCT)—compared to a common X-ray-guided technique called angiography. The trial (ILUMIEN IV) is the first large-scale randomized global study using Abbott's OCT imaging in patients with high-risk, complex coronary artery disease. Patients in the study will be randomized to either OCT-guided or traditional angiography to guide placement of one or more XIENCE everolimus-eluting coronary stents.

The first patient was enrolled by Franco Fabbiocchi, M.D., director of Invasive Cardiology Unit IV at IRCCS Centro Cardiologico Monzino in Milan, Italy.

During stent implantation guided by one of Abbott's OCT platforms, physicians use high-resolution images taken directly inside the patient's vessels to accurately measure dimension and choose a stent that best fits the vessel. OCT is also used to help physicians ensure the stent is fully expanded and is flush against a vessel wall, which are both important factors in reducing stent failure.[1,2]

The ILUMIEN IV trial will enroll up to 3,650 patients with high-risk, complex disease at 125 centers in North America, Europe and Asia to determine if OCT-guided stent procedures result in larger vessel diameters — thus, allowing increased blood flow — and whether this will improve clinical outcomes for patients compared to stent procedures guided by angiography. Patients with complex disease may have multiple, or totally blocked arteries, or other diseases such as diabetes; and these patients account for an increasing number of cases.

"Today, most of the world uses angiography for stent implantation using a two-dimensional view of the coronary artery to assess a complex three-dimensional structure. Physicians need new technology to help optimize percutaneous coronary intervention, and OCT provides just that, the ability to look at the artery from the outside-in and the inside-out," said Ziad A. Ali, M.D., director of Intravascular Imaging and Physiology at Columbia University Medical Center's Center for Interventional Vascular Therapy and co-principal investigator of the study. "I'm confident this technology will have a positive impact on clinical practice around the world and we hope to provide evidence for leading medical organizations to update clinical guidelines for stent implantation based on the results of this study."

"Abbott is committed to providing doctors and patients with life-changing technology, and there is a growing body of evidence that OCT-guided stent implantation may result in better outcomes for patients," said Charles Simonton, M.D., chief medical officer and divisional vice president of

Medical Affairs for Abbott's vascular business. "We're excited to initiate this trial to generate the groundbreaking data that would support use of OCT over angiography to achieve better outcomes for patients with high-risk disease."

The ILUMIEN IV trial's focus on high-risk patients will build on findings from the previous ILUMIEN series of trials which showed stent procedures using OCT imaging resulted in superior stent expansion and greater rates of procedural success compared to angiography, and non-inferiority to intravascular ultrasound (IVUS) in post-procedure minimal stent area (MSA).[3] Those trials also showed that use of the OCT high-resolution imaging enabled physicians to better detect damage to artery walls, called dissection, which sometimes happens during the placement of a stent compared to IVUS or angiography, which could then be repaired as necessary.[4]

About the Study:
ILUMIEN IV is a prospective, single-blind, multi-center, randomized study that will evaluate OCT-guided vs. angiography-guided coronary stent procedures in complex and high-risk patients. The primary endpoints are superiority of OCT-guided vs. angiography-guided stent implantation in achieving a larger vessel opening (post procedural lumen dimension) and improved clinical cardiovascular outcomes out to two years, defined by target vessel failure (a composite endpoint of cardiac death, target vessel myocardial infarction and ischemia-driven target vessel revascularization).

About Optical Coherence Tomography Imaging:
OCT is an intravascular imaging platform that uses light-based technology to help doctors see and measure arteries from inside the vessel with high precision. Physicians can assess and understand the degree of disease and take necessary steps to treat it. With automated, highly accurate measurements, OCT guides stent selection, placement and deployment.

For U.S. Important Safety Information, visit: https://www.vascular.abbott/content/dam/bss/divisionalsites/av/products/optis-integrated-and-mobile-software-isi.pdf.

About XIENCE:
XIENCE first received CE Mark in 2006 and FDA approval in 2008. Its safety profile is unprecedented with consistent low rates of stent thrombosis, even in complex cases. A special coating on XIENCE interacts with proteins in the blood to reduce the risk for blood clots in the stent. For more information about XIENCE, visit www.XienceStent.com/US.

For U.S. Important Safety Information, visit: https://vascular.abbott.com/Xience-Stent-Safety.html#isi

About Abbott:
At Abbott, we're committed to helping people live their best possible life 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, 99,000 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] Mintz GS, Weissman NJ. Intravascular ultrasound in the drug-eluting stent era. *J Am Coll Cardiol*. 2006 Aug 1; 48(3):421-9.

[2] Cook S, et al. Incomplete stent apposition and very late stent thrombosis after drug-eluting stent implantation. *Circulation*. 2007 May 8; 115(18):2426-34.

[3] Decision Resources Group, July 2017. Data on file at Abbott.

[4] Ali, Z. (2016, October). Optical Coherence Tomography Compared to Intravascular Ultrasound and Angiography to Guide Coronary Stent Implantation. The ILUMIEN III: OPTIMIZE PCI trial. Presented at TCT 2016, Washington D.C.

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