Abbott Initiates Clinical Trial Of Three-Month Dual Antiplatelet Therapy Following Implantation With XIENCE Coronary Stent

- Trial will evaluate amount of time patients at high risk of bleeding should receive blood thinning medicine after treatment with XIENCE

- Study to enroll approximately 2,000 patients in U.S. and Asia

ABBOTT PARK, Ill., July 25, 2017 -- Abbott today announced that the first patient has been enrolled in a clinical study evaluating the short-term use of common blood thinning medicines, called dual antiplatelet therapy (DAPT), after receiving a XIENCE everolimus-eluting coronary stent.

The study, called XIENCE Short DAPT, will evaluate if three months of DAPT is non-inferior to the current standard of 12 months after implantation with a XIENCE stent for patients who are at high risk of bleeding. The study will enroll approximately 2,000 patients at 100 sites in the U.S. and Asia.

Blood thinning medicines are prescribed for patients after stent implantation to prevent stent thrombosis, but can increase the risk for bleeding complications, particularly for high-bleeding risk patients.[1] Approximately 1 in 5 patients who receive stents today are considered at high risk of bleeding.[2]

“Limiting the duration of blood thinning medicine from 12 months to three months is particularly important for people at higher risk of bleeding due to factors such as older age, anemia, and renal disease," said Roxana Mehran, MD, FACC, FACP, FCCP, FESC, FAHA, FSCAI, professor of Medicine and director of Interventional Cardiovascular Research and Clinical Trials at the Zena and Michael A. Weiner Cardiovascular Institute at Mount Sinai School of Medicine and global principal investigator of the study. “The results of this study will help determine if doctors can safely reduce the amount of time that high bleeding-risk patients must take blood thinning medication after receiving a XIENCE stent to unblock coronary arteries.”

“Since its initial regulatory approval, XIENCE has been implanted in approximately 10 million people, and is considered the safest drug eluting stent available," said Charles Simonton, M.D., FACC, FSCAI, chief medical officer and divisional vice president of medical affairs for Abbott's vascular business. “We continue to advance XIENCE research with the goal of helping even more people return to their daily lives as quickly as possible.”

About the Study

XIENCE Short DAPT is a prospective, multi-center, open label, single-arm, non-randomized study. The primary endpoint is non-inferior rates of myocardial infarction or death in high-bleeding risk patients. Secondary endpoints include evaluation of the extent and severity of bleeding rates, stent thrombosis, stroke, revascularization, myocardial infarction and death.

About XIENCE

The XIENCE family of everolimus-eluting coronary stent systems are indicated for improving coronary luminal diameter in patients, including people with diabetes mellitus, de novo chronic total coronary occlusions, people with symptomatic heart disease due to de novo native coronary artery lesions for XIENCE V (length ≤ 28 mm), XIENCE PRIME, XIENCE Xpedition and XIENCE Alpine (lengths ≤ 32 mm) with reference vessel diameters of ≥2.25 mm to ≤ 4.25 mm.

XIENCE was approved in the U.S. in 2008, and is the most-commonly used drug-eluting stent worldwide.

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, 94,000 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] Eikelboom JW, Mehta SR, Anand SS, Xie C, Fox KA, Yusuf S. Adverse impact of bleeding on prognosis in patients with acute coronary syndromes. *Circulation* 2006;114:774–82.

[2] Shanmugam VB, Harper R, Meredith I, Malaiapan Y, Psaltis PJ. An overview of PCI in the very elderly *J Geriatr Cardiol 2015;*174–184

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