New Late-Breaking Data Show Equivalent Outcomes With Shorter Durations Of Anti-Clotting Drugs For XIENCE™ Stent Patients With High Bleeding Risk

- Results from Abbott's XIENCE™ 28 and XIENCE 90 trials demonstrate non-inferiority of shorter courses of dual antiplatelet therapy in reducing the frequency of post-stenting death, heart attacks and severe bleeding compared with 12 months of dual antiplatelet therapy in patients with high bleeding risk

- Late-breaking data confirm the consistent effect of XIENCE stent technology, when applied to complex, high bleeding risk patients

ABBOTT PARK, Ill., Oct. 15, 2020 — Abbott today announced new late-breaking data from two studies in the company's XIENCE Short DAPT program. The results demonstrate no difference between shorter courses of treatment with dual antiplatelet therapy (DAPT) compared with 12 months of DAPT following implantation of the XIENCE drug-eluting stent in patients who are at a high risk of bleeding.

DAPT is routinely prescribed after coronary stent implantation to help prevent clotting (thrombosis), which can block a blood vessel and potentially result in heart attack or death. However, DAPT can also increase the risk of bleeding complications in some patients[1]. In fact, of all patients undergoing stenting procedures, approximately one in five are considered at high risk of bleeding.[2] The new late-breaking Short DAPT data, presented during the 32nd Transcatheter Cardiovascular Therapeutics (TCT) annual scientific symposium, showed no increase in ischemic events with shorter durations of DAPT for patients who require stenting, but who may adversely respond to blood-thinning medications.

"New approaches for managing patients at high risk of bleeding after stent implantation is an important area of study, and this data around shorter durations of antiplatelet therapy offer a strong view into alternatives for these patients," said Roxana Mehran, M.D., professor of Medicine and director of Interventional Cardiovascular Research and Clinical Trials at the Zena and Michael A. Wiener Cardiovascular Institute at Icahn School of Medicine at Mount Sinai and the global principal investigator for Abbott's Short DAPT program (XIENCE 28 and XIENCE 90).

"We are encouraged by these results as they could reduce patient exposure to medications like blood thinners and provide the cardiovascular community with critical information on how it approaches the use of DAPT for at-risk patients who receive coronary stenting, " said Dr. Mehran.

Late-breaking results from the Short DAPT program of clinical trials evaluated findings from both the XIENCE 28 (1,605 patients) and XIENCE 90 (2,047 patients) studies.

The XIENCE 28 Study

In the XIENCE 28 study, physicians assessed a primary endpoint of non-inferiority comparing rates of all-cause death or myocardial infarction (MI) following XIENCE implantation in high bleeding risk patients who received either 28 days or 6 months of DAPT. Findings include:

- Treatment with DAPT for 28 days was found to be the same as treatment with 6 months of DAPT after implantation with a XIENCE stent.
- The study met the endpoint of non-inferiority of all-cause death or MI from 1 to 6 months, with an overall death or MI rate of 3.5% in patients who received 28 days of DAPT compared with 4.3% in patients who received 6 months of DAPT ($p=0.0005$).[3]
- Severe bleeding (BARC 3-5) was found to be significantly lower in patients who received 28 days of DAPT (2.2%) compared with 6 months of DAPT (4.5%; $p=0.02$).

The XIENCE 90 Study

The XIENCE 90 study investigated the non-inferiority of all-cause death or all MI from 3 to 12 months following XIENCE implantation in the same patient population as the XIENCE 28 study but compared results against 12 months of DAPT. Findings include:

- From 3 to 12 months, the risk of a blood clot in the stented area was as low as patients who received 12 months of DAPT.
- Severe bleeding was significantly lower for high bleeding risk patients (2.2% for the 90-day DAPT group compared with 6.3% for the 12-month DAPT group).

"Since the initial launch more than ten years ago, the XIENCE family of stents has become the gold-standard in coronary drug-eluting stents," said Nick West, M.D., divisional vice president, medical affairs, and chief medical officer in Abbott's vascular business. "With the Short DAPT program, our goal is ultimately to find the optimal duration of use of blood thinning medication for individual patients by providing tailored treatment options to minimize the risk of potentially fatal bleeding events and to help them return to their daily lives as quickly as possible."

For U.S. important safety information on XIENCE, visit: https://bit.ly/2QuCMCR.

About Abbott:

Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 107,000 colleagues serve people in more than 160 countries.

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[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

[3] Mehran R and Valgimighli M, Short DAPT Program XIENCE 90/28 Evaluating the Safety of 3-month and 1-month DAPT in High Bleeding Risk Patients. Data presented at TCT 2020.

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