Abbott's XIENCE Stent Receives FDA Approval For Shortest Blood Thinner Course For High Bleeding Risk Patients

- New labeling approval for Abbott's XIENCE™ stent builds on a legacy of safety and allows for one-month (as short as 28 days) dual anti-platelet therapy (DAPT) for patients at high bleeding risk (HBR)

- The new XIENCE Skypoint™ stent received FDA approval in the U.S. and CE Mark approval in Europe

- XIENCE stents have 10+ years of clinical data across 120 clinical trials, more than 125,000 patients and 15 million stent[1] implants

ABBOTT PARK, Ill., June 30, 2021 /PRNewswire/ -- Abbott (NYSE: ABT) today announced its XIENCE family of stents has received U.S. Food and Drug Administration (FDA) approval for one-month (as short as 28 days) DAPT labeling for high bleeding risk (HBR) patients in the U.S. In addition, XIENCE stents recently received CE Mark approval for DAPT as short as 28 days – giving XIENCE stents the shortest DAPT indication in the world.

In addition to the HBR indication, Abbott has also received FDA approval and European CE Mark approval for its next-generation XIENCE Skypoint stent. XIENCE Skypoint is easier to place and allows physicians to treat larger blood vessels through improved stent expansion that can open clogged vessels more effectively.

"The new FDA approval for DAPT for the XIENCE family of stents provides interventional cardiologists confidence they are delivering the best care to patients with high bleeding risk. A short DAPT duration minimizes risks for high bleeding risk patients and allows them to return to daily life sooner and with more assurance," says 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).

Stents are a critical therapy option to open blood vessels that have been clogged by calcium or fatty deposits. Following stent implantation, DAPT is routinely prescribed 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.[2] In fact, of all patients undergoing stenting procedures, approximately one in five are considered at high risk for bleeding.[3]

Patients who receive stents are typically on DAPT regimens (aspirin and P2Y12 inhibitors) for six to 12 months to prevent blood clots from blocking the stented vessel. However, HBR patients can experience side effects such as bleeding during prolonged courses of DAPT. With the shortest approved DAPT labeling, Abbott's XIENCE stents can help physicians treat their HBR patients more effectively. Abbott's XIENCE 28 and XIENCE 90[4] studies show that DAPT can be safely discontinued early as short as 28 days with no increased risk in patient adverse events, solidifying the industry-leading safety profile of the XIENCE family of stents.

XIENCE SKYPOINT: INNOVATION FOR OPTIMAL PATIENT CARE

XIENCE Skypoint, the latest in a line of trusted XIENCE stents, is now approved for use in HBR patients with one-month DAPT labeling – as short as 28 days – in the U.S. and in Europe. Supported by 10 years of clinical data, including 120 clinical trials studying 125,000 patients and the implantation of 15 million stents, XIENCE drug-eluting stents (DES) have been proven safe and effective, consistently delivering successful patient outcomes.

"Even small differences between stents can impact both short- and long-term patient outcomes, and this latest generation of the XIENCE stent offers multiple improvements that provide enhanced deliverability and expansion capability," said Nick West, M.D., chief medical officer and divisional vice president of global medical affairs at Abbott's vascular business. "As we continue to innovate at Abbott, we are delivering medical technology that improves patients' lives, while building a body of research evidence that underlines clinical consistency and patient safety."

XIENCE is supported by the largest body of DAPT patient evidence, with over 24,000 patients analyzed.[5] Abbott continues to focus on further improving the class-leading XIENCE stent platform through innovation, supported by clinical data from the most complex patient populations, including HBR, with the aim of driving optimal care for patients suffering from coronary heart disease.

Important Safety Information: XIENCE Drug-Eluting Stents | Abbott (cardiovascular.abbott)

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 109,000 colleagues serve people in more than 160 countries.

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[1] https://www.cardiovascular.abbott/us/en/hcp/products/percutaneous-coronary-intervention/xience-family.html

[2] 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.

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

[4] https://www.cardiovascular.abbott/int/en/hcp/products/percutaneous-coronary-intervention/xience-family/xience-trial-results.html

[5] Généreux P, et al. Circ Cardiovasc Interv. 2015;8(5):1-16; Natsuaki et al., Cardiovasc Interv and Ther. 2016. 31:196–209; Watanabe H, et al. JAMA. 2019;321(24):2414-2427; Hahn J, et al. ACC 2019 – SMART CHOICE; Valgimigli M, et al. Circulation. 2012;125:2015-2026; Gilard M, et al. J Am Coll Cardiol 2015;65:777-786; Hong SJ, et al. J Am Coll Cardiol Intv. 2016;9:1438–1446. Gwon HC, et al. ACC 2011 - EXCELLENT. Mehran R, et al. TCT Connect 2020. XIENCE 28/90.

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