Newest Generation Of Leading Heart Stent Is Now Approved In The U.S. For People With Coronary Artery Disease

- XIENCE Sierra™, the newest generation of XIENCE drug-eluting stents, received U.S. Food and Drug Administration (FDA) approval

- XIENCE stents are among the most-widely used and studied stents in the world and have an unparalleled safety record

- New features help doctors treat more difficult-to-reach blockages in patients' arteries

ABBOTT PARK, Ill., May 23, 2018 /PRNewswire/ -- Abbott (NYSE: ABT) today announced it received approval from the U.S. Food and Drug Administration (FDA) for XIENCE Sierra™, the newest generation of the company's gold-standard XIENCE everolimus-eluting coronary stent system. XIENCE stents are among the world's most-used and studied stents and have an exceptional safety record with low rates of complications. Design and technology advances in this generation of XIENCE include features specifically designed for the treatment of complex blockages that now account for up to 70 percent of cases.[1]

"We developed XIENCE Sierra so that physicians can more easily deliver the stent even in challenging cases," said Chuck Brynelsen, senior vice president of Abbott's vascular business. "The updated design and improved deliverability mean doctors can access and unblock difficult-to-treat lesions with more flexibility and precision than other stents."

Design innovations in XIENCE Sierra include a thinner profile, increased flexibility, longer lengths, and small diameters. The new stent and delivery system were specifically developed for the treatment of complex cases, including people with multiple or totally blocked vessels.

More than 8 million people worldwide have received a XIENCE stent since its initial regulatory approvals in the EU in 2006 and in the U.S. in 2008. Its unparalleled safety is supported in over 100 clinical trials and by 10 years of global real-world experience.[2]

Abbott received Regulatory approval for XIENCE Sierra in Japan in April 2018, and CE Mark in Europe in October 2017.

About Coronary Artery Disease:
Coronary artery disease occurs when the arteries that supply blood to the heart become hard and narrow, leading to chest pain or shortness of breath and increased risk of heart attack. To treat coronary artery disease, interventional cardiologists may perform a percutaneous coronary intervention, a non-surgical procedure that uses a catheter inserted through an artery in the leg or wrist to implant a stent that reopens vessels and allow blood to flow.

About XIENCE:
XIENCE first received CE Mark in 2006 and FDA approval in 2008. Its safety profile is unparalleled with consistent low rates of stent thrombosis, even in complex cases.[3,4] A special coating on XIENCE interacts with proteins in the blood to reduce the risk for blood clots in the stent. The XIENCE Sierra stent is implanted using a catheter that is inserted through the femoral artery in the groin or radial artery in the wrist. For more information about XIENCE, visit www.XienceStent.com/US

For U.S. Important Safety Information, visit: https://www.vascular.abbott/us/products/coronary-intervention/xience-sierra.html#prodisi

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

[2] 10,000,000 implants number is based on data of DES implants through Q1 2017. Comparative claim based on unit usage in U.S., Japan, China, India, top 5 Western Europe, and Korea. Other leading DES: BSX stents (Promus Element, Promus Element Plus, Promus Premier, Synergy); MDT stents (Resolute, Resolute Integrity, Resolute Onyx); Terumo stents (Nobori, Ultimaster); Biotronik stent (Orsiro); and Biosensors stent (BioMatrix). Data on file at Abbott Vascular.

[3] Palmerini, et al. XIENCE showed significant benefit compared to several DES and composite BMS in multiple large scale meta-analyses and other RCTs. The Lancet. 379:9824, 14-20 April 2012, pp. 1393-1402; Bangalore S, et al. Circ Cardiovasc Interv, Aug 6, 2013. doi: 10.1161/ circinterventions.113.000415.; Valgimigli, et al. Effects of Cobalt-chromium Everolimus eluting or bare metal stent on fatal and non-fatal cardiovascular events. A patient-level meta analysis. EuroPCR 2014; Serruys, PW et al. RESOLUTE All Comers Trial, NEJM 2010. Published online June 16, 2010; Fajadet, J., et al. PLATINUM PLUS 30-day Poster, TCT 2012.

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