Abbott Announces FDA Approval and U.S. Launch of Next-Generation XIENCE XpeditionT Drug Eluting Stent System

The Associated Press

Abbott (NYSE: ABT) today announced that the XIENCE XpeditionT Everolimus Eluting Coronary Stent System received U.S. Food and Drug Administration (FDA) approval and is launching immediately in the United States, providing physicians with a next-generation technology with the largest size matrix in the U.S. market. XIENCE Xpedition features a new stent delivery system designed to optimize deliverability, particularly in challenging coronary anatomies.

Samin K. Sharma, M.D., director of Clinical and Interventional Cardiology, dean of International Clinical Affiliations, and president of the Mount Sinai Heart Network at Mount Sinai Medical Center, New York, was the first physician to implant a patient with XIENCE Xpedition in the United States.

"XIENCE Xpedition represents a powerful combination of deliverability, strong clinical data and broad availability of meaningful sizes - three factors that make this product well-suited to treat a wide range of patients," said Dr. Sharma. "The impact of the changes to the stent delivery system is particularly notable in patients with complex coronary anatomy. For these patients, physicians have a new technology to reach the blockage and restore blood flow with ease and confidence." Abbott's XIENCE drug eluting stents, including the newly approved XIENCE Xpedition, are the first and only drug eluting stents in the U.S. market to be proven safe for direct stenting. Direct stenting, a technique in which the stent system is not preceded by another device (such as a balloon dilatation catheter) to prepare the lesion, has the potential to save time and resources in the catheterization laboratory. XIENCE Xpedition is supported by robust clinical evidence from the XIENCE family of drug eluting stents, including data from more than 45,000 patients across more than 100 studies, with long-term outcomes out to five years. Data have consistently shown an excellent safety profile for the XIENCE family of stents.

"The launch of XIENCE Xpedition in the United States will advance Abbott's worldwide market-leading position in drug eluting stents," said John M. Capek, Ph.D., executive vice president, Medical Devices, Abbott. "XIENCE Xpedition leverages the strong clinical outcomes of XIENCE V and XIENCE PRIME while providing important advantages in deliverability. With its redesigned stent delivery system and a full matrix of sizes, XIENCE Xpedition provides physicians with a comprehensive, trusted option to treat a broad range of patients with coronary artery disease." XIENCE Xpedition will be available in the largest size matrix in the U.S. market, with both rapid exchange (RX) and over-the-wire (OTW) configurations, providing physicians with the most popular delivery platforms. XIENCE Xpedition has diameters ranging from 2.25 mm to 4 mm, including a unique 3.25 mm diameter, and lengths from 8 mm to 38 mm, for more accurate vessel sizing.

About the XIENCE Family of Drug Eluting Stents XIENCE Xpedition is available in the United States, Europe, the Middle East and parts of Asia. XIENCE PRIME@and [1] XIENCE V@are [2] available in countries throughout the world.

In the United States, XIENCE Xpedition and XIENCE PRIME are indicated for improving coronary artery luminal diameter in patients with symptomatic heart disease due to de novo native coronary artery lesions (length ? 32 mm) with reference vessel diameters of ? 2.25 mm to ? 4.25 mm. Additional information, including important safety information, about XIENCE Xpedition is available at www.xiencestent.com [3] or http://www.abbottvascular.com/static/cms_workspace/pdf/ifu/coronary_inte... [4] and for XIENCE PRIME at http://www.abbottvascular.com/static/cms_workspace/pdf/ifu/coronary_inte... [5].

In the United States, XIENCE V and XIENCE nano@ are indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to de novo native coronary artery lesions (length ?28 mm) with reference vessel diameters of 2.25 mm to 4.25 mm. Additional information about XIENCE V and XIENCE nano, including important safety information, is available at www.xiencestent.com [3] or http://www.abbottvascular.com/static/cms_workspace/pdf/ifu/coronary_inte... [6].

Everolimus is an anti-proliferative drug used in Abbott's XIENCE coronary stent systems. Everolimus was developed by Novartis Pharma AG and is licensed to Abbott by Novartis for use on its drug eluting vascular devices. Everolimus has been shown to inhibit in-stent neointimal growth in the coronary vessels following stent or scaffold implantation.

About Abbott Vascular Abbott Vascular is the world's leader in drug eluting stents. Abbott Vascular has an industry-leading pipeline and a comprehensive portfolio of market-leading products for cardiac and vascular care, including products for coronary artery disease, vessel closure, endovascular disease and structural heart disease.

About Abbott Abbott is a global healthcare company devoted to improving life through the development of products and technologies that span the breadth of healthcare. With a portfolio of leading, science-based offerings in diagnostics, medical devices, nutritionals and branded generic pharmaceuticals, Abbott serves people in more than 150 countries and employs approximately 70,000 people.

Visit Abbott at www.abbott.com [7] and connect with us on Twitter at @AbbottNews.

SOURCE Abbott -0- 01/03/2013 /CONTACT: Media, Jonathon Hamilton, +1-408-845-3491; Financial, Tina Ventura, +1-847-935-9390 /Web Site: http://www.abbott.com [7] (NYSE:ABT) / CO: Abbott IN: HEA MTC PHA SU: FDA PDT PRN -- AQ36092 -- 0000 01/03/2013 13:30:00 EDT http://www.prnewswire.c [8]

Source URL (retrieved on *05/26/2013 - 12:06am*):
http://www.mdtmag.com/news/2013/01/abbott-announces-fda-approval-and-us-launch-next-generation-xience-xpeditiont-drug-eluting-stent-system?qt-most_popular=0&qt-recent_content=0

Links:
[1] mailto:PRIME@and
[2] mailto:V@are
[3] http://www.xiencestent.com
[4] http://www.abbottvascular.com/static/cms_workspace/pdf/ifu/coronary_intervention/eIFU_Xience_Xpedition.pdf
[5] http://www.abbottvascular.com/static/cms_workspace/pdf/ifu/coronary_intervention/eIFU_XIENCE_PRIME_XIENCE_PRIME_LL.pdf
[6] http://www.abbottvascular.com/static/cms_workspace/pdf/ifu/coronary_intervention/eIFU_XIENCE_V_XIENCE_nano.pdf
[7] http://www.abbott.com
[8] http://www.prnewswire.c