

**For Immediate Release**



## News

### Health Canada Approves Abbott's XIENCE V<sup>®</sup> Drug Eluting Stent

*New Drug Eluting Stent Offers Outstanding Combination of Deliverability, Safety and Efficacy*

ABBOTT PARK, Ill., Aug. 24, 2009 – Abbott announced today that it has received approval from Health Canada for the XIENCE V<sup>®</sup> Everolimus Eluting Coronary Stent System for the treatment of coronary artery disease (CAD). XIENCE V is the only drug eluting stent to have demonstrated superiority over the TAXUS<sup>®</sup> Paclitaxel-Eluting Coronary Stent System (TAXUS) in the primary endpoints of two randomized, pivotal (phase III) clinical trials. Abbott will launch XIENCE V in Canada immediately.

"XIENCE V is an important next-generation treatment option combining impressive deliverability with demonstrated efficacy and safety," said Guy Leclerc, M.D., FRCPC, FACC, interventional cardiologist and associate professor of research, Centre Hospitalier de l'Université de Montréal. "With strong, long-term data supporting it, XIENCE V is a welcome addition for treating patients with coronary artery disease."

Cardiovascular disease is the leading cause of death in Canada.<sup>1</sup> Furthermore, 54 percent of all cardiovascular deaths are due to CAD, whereby plaque buildup narrows the arteries and reduces blood flow to the heart, which can lead to chest pain or a heart attack.<sup>1</sup>

The XIENCE V drug coated stent is used to treat CAD by propping open a narrowed or blocked artery and releasing the drug, everolimus, in a controlled manner over time to help prevent the artery from becoming blocked again following the stent procedure.

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<sup>1</sup> Heart and Stroke Foundation web site, accessed June 30, 2009

(<http://www.heartandstroke.com/site/c.iKlQLcMWJtE/b.3483991/k.34A8/Statistics.htm#heartdisease>)

"XIENCE V represents a major advancement in the treatment of heart disease, based upon its ease of use and consistently strong performance across all clinical trials. This is why physicians have embraced XIENCE V, making it the market-leading drug eluting stent around the world," said Robert Hance, senior vice president, vascular, Abbott. "We look forward to launching XIENCE V immediately in Canada to meet physician demand for this much-awaited drug eluting stent technology."

"XIENCE V is a highly deliverable drug eluting stent that has been studied in thousands of patients around the world, including more than 200 patients in Canada," said David Simpson, general manager, Abbott Vascular Canada. "The launch of XIENCE V in Canada marks an important milestone, as physicians and patients now have access to what has become a new standard in drug eluting stents."

#### **Outstanding Clinical Evidence for XIENCE V**

The clinical program for XIENCE V studied patients in the United States, Canada, Europe, South Africa and Asia-Pacific, and demonstrated excellent long-term results and data on "real-world" patients from the SPIRIT family of trials.

In long-term data from the SPIRIT III<sup>^</sup> trial of 1,002 patients, XIENCE V continued to demonstrate positive clinical benefits for patients out to two years. XIENCE V demonstrated a 45 percent reduction in the risk of major adverse cardiac events (MACE) compared to TAXUS (7.3 percent for XIENCE V vs. 12.8 percent for TAXUS)\* at two years. MACE is an important composite clinical measure of safety and efficacy outcomes for patients, and is defined as a composite of cardiac death, heart attack (myocardial infarction or MI), or ischemia-driven target lesion revascularization (ID-TLR driven by lack of blood supply) for the SPIRIT III trial. XIENCE V also demonstrated a low rate of stent thrombosis between one and two years per Academic Research Consortium (ARC) definition of definite/probable stent thrombosis (0.3 percent for XIENCE V vs. 1.0 percent for TAXUS). The ARC definitions of stent thrombosis were developed to eliminate variability in the definitions across various drug eluting stent trials.

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<sup>^</sup> In the SPIRIT III trial, TAXUS Express2 was used as the control.

In March 2009, Abbott presented long-term data from the SPIRIT II<sup>‡</sup> clinical trial of 300 patients, which showed that patients treated with XIENCE V continue to experience fewer heart attacks, deaths or repeat procedures at the target lesion compared to patients treated with TAXUS out to three years. XIENCE V demonstrated a 57 percent reduction in the risk of MACE compared to TAXUS at three years (6.4 percent for XIENCE V vs. 14.9 percent for TAXUS)\*. For the SPIRIT II trial, MACE is defined as a composite of cardiac death, MI, or ID-TLR driven by lack of blood supply.

In addition, there was no occurrence of stent thrombosis between two and three years with XIENCE V in the SPIRIT II trial, and a low rate of stent thrombosis from zero to three years, per ARC definition of definite/probable stent thrombosis (0.9 percent for XIENCE V vs. 2.8 percent for TAXUS)\*.

In May 2009, Abbott presented one-year data from the SPIRIT V (five) international, single-arm study, which evaluated XIENCE V in 2,663 patients – including more than 200 patients enrolled at seven sites across Canada. XIENCE V demonstrated low rates of repeat procedure (target lesion revascularization or TLR), stent thrombosis and MACE in a diverse, "real world" population of patients and lesion types, including patients with diabetes, patients with multi-vessel disease and patients with highly complex lesions. In the SPIRIT V study, XIENCE V demonstrated a very low 1.8 percent rate of TLR, a 0.7 percent rate of definite/probable stent thrombosis and a 5.1 percent rate of MACE at one year. For the SPIRIT V trial, MACE is defined as a composite of cardiac death, heart attack (myocardial infarction not clearly attributed to a non-target vessel), or TLR.

### **More About XIENCE V**

XIENCE V is built upon Abbott's market-leading bare metal stent, the MULTI-LINK VISION<sup>®</sup> Coronary Stent System. The VISION platform is designed to facilitate ease of delivery, making it easier for physicians to maneuver the stent and treat the diseased portion of the artery.

The XIENCE V drug coated stent will be available on both over-the-wire (OTW) and rapid exchange (RX) delivery systems. Rapid exchange is the most widely used type of delivery system because it provides physicians additional flexibility to work as single operators during stent procedures.

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\* Event rates based on Kaplan-Meier estimates.

<sup>‡</sup> Both TAXUS Express2 (73 percent of lesions) and TAXUS Liberte (27 percent of lesions) were used as controls in the SPIRIT II trial.

Abbott's market-leading XIENCE V drug eluting stent is marketed in the United States, Europe and other international markets. XIENCE V is an investigational device in Japan and is currently under review by Japan's Ministry of Health, Labour and Welfare and the Pharmaceuticals and Medical Devices Agency.

Abbott supplies a private-labeled XIENCE V to Boston Scientific called the PROMUS™ Everolimus-Eluting Coronary Stent System. PROMUS is manufactured by Abbott and supplied to Boston Scientific as part of a distribution agreement between the two companies.

Everolimus, developed by Novartis Pharma AG, is a proliferation signal inhibitor, or mTOR inhibitor, licensed to Abbott by Novartis for use on its drug eluting stents. Everolimus has been shown to inhibit in-stent neointimal growth in the coronary vessels following stent implantation, due to its anti-proliferative properties.

XIENCE V is indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to *de novo* native coronary artery lesions (lesions ≤ 28 mm) with reference vessel diameters of 2.5 mm to 4.25 mm. Additional information about XIENCE V, including important safety information, is available online at [www.xiencev.com](http://www.xiencev.com) or [www.abbottvascular.com/en\\_US/content/document/eIFU\\_XienceV.pdf](http://www.abbottvascular.com/en_US/content/document/eIFU_XienceV.pdf).

#### **About Abbott Vascular**

Abbott Vascular, a division of Abbott, is one of the world's leading vascular care businesses. Abbott Vascular is uniquely focused on advancing the treatment of vascular disease and improving patient care by combining the latest medical device innovations with world-class pharmaceuticals, investing in research and development, and advancing medicine through training and education. Headquartered in Northern California, Abbott Vascular offers a comprehensive portfolio of vessel closure, endovascular and coronary products.

#### **About Abbott**

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs more than 72,000 people and markets its products in more than 130 countries. Abbott has been operating in Canada since 1931 and its Canadian operations are headquartered in Montreal, Quebec. Abbott Canada employs more than 2,000 people.

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