



Fact Sheet

XIENCE V[®] Drug Eluting Stent

Key Facts

- The XIENCE V Everolimus Eluting Coronary Stent System is the only drug eluting stent (DES) to demonstrate superiority versus Taxus in two randomized, head-to-head, pivotal (phase III) clinical trials
- XIENCE V is an important next-generation treatment option combining impressive deliverability with demonstrated efficacy and safety
- The proven design of the MULTI-LINK VISION[®] Coronary Stent System, which XIENCE V is built upon, allows for ease of stent delivery to the blocked portion of the artery



Overview

The XIENCE V[®] Everolimus Eluting Coronary Stent System was approved in the United States in July 2008 and internationally in October 2006. This next-generation drug eluting stent (DES) is used to treat coronary artery disease (CAD) by propping open a narrowed or blocked artery and releasing the drug, everolimus, in a controlled manner to prevent the artery from renarrowing following a stent procedure. XIENCE V is the only DES to demonstrate superiority versus Taxus[®] in two randomized, head-to-head, pivotal (phase III) clinical trials. In the SPIRIT II trial of 300 patients, XIENCE V demonstrated superiority to the TAXUS[®] paclitaxel-eluting coronary stent systems in the trial's primary endpoint of in-stent late loss, with a statistically significant 69 percent reduction at six months (0.11mm vs 0.36mm). Both TAXUS[®] Express^{2™} (73% of lesions) and TAXUS[®] Liberte[®] (27% of lesions) were used as controls in the SPIRIT II trial. In the SPIRIT III trial of 1,002 patients, XIENCE V demonstrated superiority to TAXUS Express² in the trial's primary endpoint of in-segment late loss (a measure of vessel renarrowing after a stent procedure), with a statistically significant 50 percent reduction at eight months (0.14mm vs 0.28mm).

Proven Design

XIENCE V is built upon the proven MULTI-LINK VISION[®] Coronary Stent System, which facilitates ease of delivery with a flexible design. Each element – the drug that is used, the concentration of the drug, the rate of elution, the composition of the polymer

coating, the stent platform and the delivery system – is important in overall clinical safety and efficacy outcomes.

- XIENCE V is easily delivered to the narrowed or blocked artery, as it has the thinnest DES platform available
- The proven polymer coating on XIENCE V facilitates the release of the drug everolimus, getting it to the right place at the right time
- Everolimus has been shown to reduce tissue growth and inflammation – two factors tied to restenosis, or the renarrowing of an artery following a stent procedure

Additional Clinical Data

Data from the SPIRIT trials continue to demonstrate efficacy and safety for patients. Two-year data from the pivotal SPIRIT III clinical trial, which compares XIENCE V to TAXUS Express², include:

- A 45 percent reduction in the risk of major adverse cardiac events (MACE – an important clinical measure of safety and efficacy outcomes for patients including cardiac death, heart attack and the need for retreatment) at two years compared to TAXUS Express² (7.3% for XIENCE V vs. 12.8% for TAXUS Express²).
- A 32 percent reduction in the risk of target vessel failure (TVF – a composite measure of safety and efficacy outcomes related to the treated vessel including cardiac death, heart attack and target vessel revascularization) compared to TAXUS Express² (10.7% for XIENCE V vs. 15.4% for TAXUS Express²).

The SPIRIT Family of Trials

Abbott is committed to the long term, careful follow-up of patients in XIENCE V studies for years to come. The SPIRIT Clinical Trial Program includes eight different trials to evaluate XIENCE V for the treatment of CAD. These studies include:

- SPIRIT FIRST – A first-in-man study comparing XIENCE V with the MULTI-LINK VISION metallic stent system in 60 patients
- SPIRIT II – A 300 patient randomized, single-blind prospective clinical trial evaluating XIENCE V versus TAXUS (Express² and Liberte) in Europe and Asia Pacific
- SPIRIT III – A large-scale pivotal clinical trial comparing XIENCE V to TAXUS Express² in 1,002 patients in the United States
- SPIRIT IV – A 3,690 patient continued access trial to evaluate the safety and efficacy of XIENCE V for the treatment of CAD in a more complex patient population in the United States
- SPIRIT V – An international clinical trial that provides additional clinical experience with XIENCE V in approximately 3,000 patients at approximately

100 clinical sites in Europe, Asia, Canada (including 7 Canadian sites) and Latin America

- XIENCE V SPIRIT WOMEN – The world's first DES trial to study only women, will evaluate 2,000 women receiving stents and the performance of XIENCE V in those patients in Europe, Asia-Pacific, Canada and Latin America
- XIENCE V USA: As part of its commitment to advancing the treatment of vascular disease, this post-market registry will evaluate outcomes in at least 5,000 patients with follow-up out to five years.
- XIENCE V INDIA: Similar to XIENCE V USA, this post-market registry will evaluate clinical outcomes in approximately 1,000 patients in India with follow-up out to five years.

Across its entire continued access and post-approval program, Abbott projects enrolling more than 14,000 XIENCE V patients.

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