



Fact Sheet

The SPIRIT Clinical Trial Program

The SPIRIT Clinical Trial Program consists of seven studies evaluating the XIENCE V™ Everolimus Eluting Coronary Stent System for the treatment of coronary artery disease: SPIRIT FIRST, SPIRIT II, SPIRIT III, SPIRIT IV, SPIRIT V, SPIRIT WOMEN and XIENCE V USA. Abbott's robust continued access and post-approval program is projected to enroll more than 14,000 XIENCE V patients across a variety of planned clinical trials.

XIENCE V was approved by the United States Food and Drug Administration (FDA) in July 2008 and was launched in Europe and Asia Pacific in 2006. The next-generation drug eluting stent utilizes the drug everolimus and the highly deliverable and proven MULTI-LINK VISION® coronary stent platform. Everolimus has been shown to reduce tissue proliferation in the coronary vessels following stent implantation. XIENCE V also features a biocompatible coating that elutes everolimus in a controlled fashion. XIENCE V is neither approved nor available for sale in Japan.

SPIRIT FIRST

SPIRIT FIRST was a first-in-man study comparing the XIENCE V stent with the MULTI-LINK VISION bare metal stent. SPIRIT FIRST was a prospective, randomized, single-blind trial evaluating XIENCE V versus MULTI-LINK VISION in *de novo* (previously untreated) lesions in 60 patients outside the United States. The primary endpoint of in-stent late loss at six months was met, with XIENCE V demonstrating an 88 percent reduction compared to MULTI-LINK VISION (0.10 mm for XIENCE V vs. 0.85 mm for VISION, p-value<0.0001). In-stent late loss is a measure of vessel renarrowing within the margins of the stent.

SPIRIT FIRST demonstrated positive results with one major adverse cardiac event (MACE) at one year and no additional MACE events out to four years. MACE is an important composite clinical measure of safety and efficacy outcomes for patients, defined as cardiac death, heart attack (myocardial infarction), or ischemia-driven target lesion revascularization (TLR, driven by lack of blood supply). XIENCE V demonstrated no early or late stent thrombosis out to four years under the

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Dublin/Academic Research Consortium (ARC) definition of late-stent thrombosis (blood clotting events in stents more than 30 days post-procedure). The ARC definition of stent thrombosis was developed to eliminate variability in the definitions across various drug eluting stent trials.

SPIRIT II

SPIRIT II is a 300-patient randomized, single-blind, prospective clinical trial evaluating the XIENCE V stent system versus the TAXUS[®] Paclitaxel-Eluting Coronary Stent System in Europe and Asia Pacific. The SPIRIT II study was designed to provide additional clinical data to support the launch of the XIENCE V system in several countries outside the United States.

In the study's primary endpoint of in-stent late loss at six months, XIENCE V demonstrated superiority to TAXUS, with a statistically significant 69 percent reduction compared to TAXUS (0.11 mm for XIENCE V vs. 0.36 mm for TAXUS, P_{NI} and $P_{SUP} < 0.0001$).

In the important clinical endpoint of MACE, data from SPIRIT II demonstrated continued positive clinical results for XIENCE V at two years with an observed 40 percent reduction in MACE compared to TAXUS (6.6 percent XIENCE V, 11 percent TAXUS). XIENCE V also demonstrated and observed 44 percent reduction in vessel retreatment (ischemia-driven TLR) compared to TAXUS at two years (3.8 percent XIENCE V, 6.8 percent TAXUS). Rates of definite/probable stent thrombosis as defined by the ARC were 0.9 percent for XIENCE V and 1.4 percent for TAXUS at two years.

The two-year data was presented at the SCAI Annual Scientific Sessions in Partnership with the ACC i2 Summit in March 2008.

SPIRIT III

SPIRIT III is a prospective, randomized, single-blind pivotal clinical trial comparing the performance of the XIENCE V stent system to the TAXUS stent system in 1,002 patients in the United States. The SPIRIT III trial met its primary endpoint, with XIENCE V demonstrating superiority to TAXUS on in-segment late loss at eight months with a statistically significant 50 percent reduction compared to TAXUS (0.14 mm for XIENCE V vs. 0.28 mm for TAXUS, $P_{NI} < 0.0001$, $P_{SUP} = 0.004$).

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In-segment late loss is a measure of vessel renarrowing in the treated vessel segment.

Long-term results from SPIRIT III demonstrated a 45 percent reduction in the risk of MACE compared to TAXUS at two years (7.3 percent XIENCE V, 12.8 percent TAXUS, p-value=0.004) *. XIENCE V demonstrated a 32 percent reduction in the risk of target vessel failure (TVF) compared to TAXUS at two years (10.7 percent XIENCE V, 15.4 percent TAXUS, p-value=0.04)*. TVF is a measure of cardiac events related to the treated vessel and includes cardiac death, heart attack or target vessel revascularization (TVR).

XIENCE V also demonstrated a low rate of stent thrombosis between one and two years, defined as very late stent thrombosis, per the ARC definition of definite/probable stent thrombosis (0.3 percent XIENCE V, 1.0 percent TAXUS).

Two-year data from the SPIRIT III trial were presented during the late-breaking clinical trials session at EuroPCR in May 2008. Results of SPIRIT III supported the July 2008 FDA approval of XIENCE V in the United States, and are intended to support approval by the Japanese Ministry of Health, Labor and Welfare.

SPIRIT IV

SPIRIT IV is a 3,690-patient continued access trial that will evaluate the safety and efficacy of the XIENCE V stent system compared to the TAXUS stent system for the treatment of coronary artery disease in a more complex patient population. This single-blind, randomized, multi-center U.S. study further evaluates the XIENCE V system for the treatment of up to three *de novo* native coronary artery lesions, with a maximum of two lesions per epicardial vessel. The primary endpoint of the trial is MACE at 12 months. Patients will be followed out to five years. Enrollment was completed in July 2008 and primary endpoint results will be presented in 2009.

SPIRIT V

SPIRIT V is an international clinical trial that will provide additional clinical experience with XIENCE V in approximately 3,000 patients at approximately 100 sites clinical sites throughout Europe, Asia, Canada and Latin America. The SPIRIT V Clinical Evaluation consists of two concurrent studies: the Registry and the Diabetic Study.

* Event rates based on Kaplan-Meier estimates; p-values are for descriptive purposes only.

The SPIRIT V Registry is a prospective, single arm, multi-center registry evaluating the performance of XIENCE V in real-world clinical settings. The SPIRIT V Diabetic Study is a prospective, randomized, active-controlled, single-blind, parallel two-arm multi-center study comparing XIENCE V to TAXUS® Liberté™ in the treatment of diabetic patients with coronary artery lesions who meet the eligibility criteria.

Early data from the SPIRIT V registry supported the efficacy, safety and success of XIENCE V in real-world use in a complex, global patient population, which includes 30 percent diabetic patients and 29 percent patients with more than one lesion being treated. At 30 days, XIENCE V had a 99 percent acute device success rate and a 98 percent procedural success rate, affirming the ease of use of the stent system. Overall rates of cardiac death (0.4 percent) and heart attack (2.0 percent) were consistently low at 30 days, regardless of patient subset. Further confirming the safety of XIENCE V, there were low rates of sub-acute stent thrombosis (0.3 percent) at 30 days in the SPIRIT V registry. These 30-day data were presented at the 2008 European Society of Cardiology (ESC) Congress in September 2008.

SPIRIT WOMEN

SPIRIT WOMEN is the world's first drug eluting stent trial to study only women and will evaluate the characteristics of 2,000 women undergoing stent implantation as well as the performance of XIENCE V in those patients in Europe, Asia-Pacific, Canada and Latin America. The study, which is currently enrolling patients, will evaluate patient and disease characteristics specific to women as well as treatment outcomes such as rate of death, heart attack and TVR and potential risk of stent thrombosis.

XIENCE V USA

XIENCE V USA is a 5,000 patient post-FDA approval trial designed to evaluate the safety and effectiveness of XIENCE V in a real-world clinical setting with follow-up out to five years. The study, which began enrolling patients in July 2008, will also evaluate patient compliance with antiplatelet therapy.

The primary endpoint of the trial is a measure of stent thrombosis every year out to five years, as defined by the ARC. The co-primary endpoint is a composite rate of cardiac death and any heart attack (Q-wave or non-Q wave myocardial infarction) in patients at one year. Secondary endpoints of the trial include patient compliance with

prescribed anti-platelet medication, measures of re-treatment by stenting or surgery, and device and procedural success.

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