XIENCE PRIME SV
Everolimus Eluting Coronary Stent
Post Marketing Surveillance

Protocol number: 12-303

Execution Overview

【2.25 mm diameter】

Abbott Vascular Japan

The Ministry of Health, Welfare and Labor requires this post-marketing surveillance as a condition of XIENCE PRIME Everolimus Eluting Coronary Stent System approval. Your kind cooperation in this surveillance will be highly appreciated.

＜This is a translation of the Japanese Version Created on: 3/15/2013　Ver. 1.0＞

Approval Number	22500BZX00070000
Approval Date	March 7, 2013
Generic Name of the Device	Coronary Stent
Brand Name of the Device	XIENCE PRIME SV Everolimus Eluting Coronary Stent
Surveillance Period	March 07, 2013 – December 31, 2019
Sponsor	Abbott Vascular Japan Co., Ltd. 3-5-27 Mita, Minato-ku, Tokyo 108-6304
Authorized Representative in Japan	Noriyuki Niki Post-marketing surveillance, Clinical Research Department Abbott Vascular Japan Co., Ltd.

1. PURPOSE OF THIS SURVEILLANCE

This post-marketing surveillance (hereinafter referred to as "the PMS") is to be conducted for a medical device prescribed in Paragraph 1 in Article 14 of the Pharmaceutical Affairs Law (Law No. 145, August 10, 1960, hereinafter referred to as "PAL") by a marketing approval holder or restrictive foreign approval holder of medical device prescribed in the standard for post-marketing surveillance and post-marketing study (excluding those set forth in Ministerial Ordinance Concerning the Standards for Executing Clinical Tests on Medical Devices, Ministerial Ordinance No. 36, March 23, 2005), which is part of the standard established by the Minister of Health, Welfare and Labor set forth in Paragraph 4 in Article 14-4 and Paragraph 4 in Article 14-6 (including when applied mutatis mutandis to Paragraph 4 in Article 19 of PAL). The objectives of the PMS are to observe the frequency, type, and degree of device deficiency to assure the safety of the new medical device as well as to collect information on evaluation of the efficacy and safety for reevaluation.

The PMS is to be conducted in accordance with Ministerial Ordinance Concerning the Standards for Post-marketing Surveillance and Tests of Medical Devices (Ministerial Ordinance No. 36, March 23, 2005, hereinafter referred to as "Good Post-marketing Study Practice: GPSP").

2. ELIGIBILITY AND PLANNED REGISTRATION

2.1 Target Patient Population

Based on GPSP regulation, general patient population with ischemic heart disease who are eligible for treatment with XIENCE PRIME SV Everolimus Eluting Stent (Approval Number: 22500BZX00070000; Approval Date: March 7, 2013) , will be registered, with no particular inclusion/exclusion criteria, and may be eligible for angiographic follow-up at eight months and clinical follow-up at one year.

2.2 Enrollment Method

- Patient informed consent is required for registration of this PMS In cases where patient informed consent (or providing some type of information) is required for PMS per the participating site policy, the Sponsor will cooperate as needed.
- If it is known at the time of index procedure that the patient is not able to return for the 8-month follow-up visit for angiogram and for the 1-year clinical follow-up, then the patient should not be registered in the PMS.
- Patients who are treated (stent delivery system inserted into the body) by XIENCE PRIME SV will be registered (including provisional stenting for side branch treatment but excluding bail-out only use)
    - The observations will be compiled on a per-patient basis even if multiple stents are implanted during the index procedure.

- A patient whose side-branch is treated by XIENCE PRIME SV can be registered. In such a case, main vessel should be treated by XIENCE PRIME.
- A patient who are treated by other DES for planned stent and XIENCE PRIME SV for bail-out purpose cannot be registered.
- Additional revascularization procedures as a part of AE treatment and planned staged procedures will not be considered as another registration, or adverse events.
- A patient who is treated, but failed to be implanted by XIENCE PRIME SV and finally treated by other devices only (No XIENCE PRIME SV are implanted) must also be registered. In such a case, only the stent information, device deficiency information and reportable adverse events related to the PRIME stent, if any, are required to be captured. Follow-up of the patient who does not receive any XIENCE PRIME SV stent is not required.

- A patient may have another lesion(s) that may be treated by larger diameter stent(s). In such a case, treatment by XIENCE PRIME is preferable. Lesion(s) treated by other than XIENCE PRIME is not considered as the target lesion.

2.3 Number of Patients to be Registered

The goal is to register 300 patients from approximately 30 sites.

MACE (composite of cardiac death, myocardial infarction and ischemia-driven target lesion revascularization) rate of this surveillance is expected to be 15%, based on past trials. For 300 patients, half of 95% confidence interval of MACE rate of 15% is 4.2%. This is 28% of expected MACE rate of 15%. This range will be enough to evaluate safety and efficacy of XIENCE PRIME SV in real world practice in Japanese hospitals.

3. PMS DURATION

Duration of patient registration for the PMS will not be set, however the target is to complete registry by June 30th, 2014.

Annual reports will be submitted to PMDA every year. After the re-submission, data will continue to be collected until 5 year follow-up is complete for all patients.

Patient data from the following time points will be collected

- Baseline (before procedure)
- Procedure
- Post-Procedure through discharge
- 8 months follow-up (follow-up angiogram)
- 1 year post-procedure (site visit is recommended but telephone contact is allowed)
- 2 year post-procedure (site visit/telephone contact)
- 3 year post-procedure (site visit/telephone contact)
- 4 years post-procedure (site visit/telephone contact)

- 5 years post-procedure (site visit/telephone contact)

4. PATIENT TREATMENT

Patient treatment strategy should be determined by the physicians based on standard PCI procedure at each of the sites. Physicians should review the most updated IFU, and carefully consider contraindications, warnings, and precautions when considering patient treatment.

Although dual antiplatelet management is ultimately determined by physicians, enrolled patients will be encouraged to receive adjunctive antiplatelet therapy consisting of an indefinite duration of aspirin in addition to a required minimum of 12 months of thienopyridine (clopidogrel, ticlopidine, etc.). It is recommended that physicians review the requirements of the most recent thienopyridine IFU before treating patients.

5. OBSERVATION ITEMS AT EACH TIME POINT

5.1 Baseline Information

1) Patient Basic Information

- Index Procedure Date (Date of Registration)
- Birth year and month
- Implant of XIENCE PRIME STENT (Only basic information, non-implant stent form and device deficiency form must be completed in the case all PRIME stents are failed to implant)
- Gender
- Height
- Weight
- Admission and Discharge dates

2) Cardiac Status at the Index Procedure and Cardiac History

- Cardiac Status (Symptom of ischemia) at the Index Procedure
- History of Myocardial Infarction
- Previous CABG
- Previous PCI

3) Risk Factors

- Family History of Premature Coronary Artery Disease

- Smoking History
- Hypertension
- Dyslipidemia
- Diabetic Mellitus
- Renal Disease
- History of Stroke
- History of Major Bleeding
- Unstable Arrhythmia
- Chronic Anticoagulant Therapy

4) Pre-Procedure ECG

5) Pre-Procedure Cardiac Enzyme and Creatinine

- Cardiac Enzyme
  - CK
  - CK-MB (If MI is suspected then must be measured per site standard practice)
- Serum Creatinine

6) Pre-Procedure Antiplatelet

- Aspirin
- Clopidogrel
- Ticlopidine
- Other anti-platelet medications
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5.2 Procedure Information

1) General Information

- Physician Name
- Procedure Start Time (Insertion of Guide Catheter)
- Procedure End Time (Removal of Guide Catheter)
- Access Site
- Number of Diseased Vessels
- Number of Treated Lesions
  - Treated only by XIENCE PRIME (Target Lesion)
  - Treated by XIENCE PRIME and Other Stent (Target Lesion)
  - Treated only by other devices (Non-target Lesion)

- LVEF

2) Lesion Information

Angiographic corelab analysis data will be adopted when it is applicable.

- Lesion Number
- Target or Non-target Lesion
- AHS Lesion Segment Number
- Lesion Type (de novo or restenosis)
- Complex Lesion
- Thrombectomy
- Lesion Preparation (pre-dilatation)
- Post-dilatation
- Use of Bailout Stent
- Total Number of Stents Implanted
- Other concomitant device (including intravascular imaging modalities), if any
- Stent recross by intravascular imaging modalities
  - Type of imaging modalities

3) Bifurcated Lesion (If applicable)

- Side Branch AHA Segment
- Bifurcation Lesion Type
- Technique Used
- Kissing Balloon

4) Lesion Visual Assessment (Pre and Post Procedure)

Angiographic corelab analysis data will be adopted when it is applicable.

- Lesion Length
- Reference Vessel Diameter
- %DS
- TIMI Flow

5) Stent Information

- Stent information must be recorded per lesion
  - Length and Diameter

- Deployment Pressure
- Successful Deployment
- Deployed Vessel (main vessel or side branch)

5.3 Post Procedure Information

1) Post-Procedure ECG

2) Post-Procedure

- Cardiac Enzyme
  - CK
  - CK-MB (If MI is suspected then must be measured per site standard practice)

5.4 Post-Procedure (Maintenance) Antiplatelet

- Type
- Start Date
- Daily Dose
- Termination or Continuation

5.5 Eight Months Follow-up

1) General Information

- Contact Method
- Contact Date
- Reportable adverse event since the last follow-up
- Change or termination of antiplatelet therapy
- Device Deficiency
- Follow-up Angiogram
- Ischemic Symptoms
- Revascularization

2) Angiographic Information

Angiographic corelab analysis data will be adopted when it is applicable.

- Lesion Length (if restenosis exist)
- Reference Vessel Diameter

- %DS

5.6 1~5 Years Follow-up (Every Year)

- Contact Method
- Contact Date
- Reportable adverse event since the last follow-up
- Change or termination of antiplatelet therapy
- Device Deficiency

5.7 Unscheduled Visit (Reportable AE related)

Complete AE form(s) if a patient visits the hospital with reportable adverse event(s).

5.8 Device Deficiency

- Date of deficiency
- Type of deficiency
- Did the device deficiency result in an adverse event?
- Description of deficiency/comment
- Product details (lot, serial numbers, etc.)

5.9 Adverse Event (Reportable Event)

Record the following adverse events (including procedural complications) and their details.

- All Coronary artery related adverse events*
  - Ischemic symptoms, evidences, including test results
  - Diagnostic angiogram
  - Revascularization
- All serious adverse events**
- All events for which relationship to the PMS Device cannot be ruled out, and
- All other adverse events related to taking antiplatelet medication(s)

* Send images to the corelab if revascularization is done to the target vessel.
** Serious adverse event: death, life-threatening, hospitalization (initial or prolonged), disability or permanent damage, congenital anomaly/birth defect, other serious (investigator's judgment).

Evaluate and record relationship of the above adverse events to the Device, procedure, and antiplatelet therapy, as well as the outcome of each event. If the event is an SAE, record the criteria for considering the event as an SAE.

6. EVALUATION ITEMS

6.1 Important Evaluation Items

Important evaluation items in this PMS are;

1) Stent Thrombosis
2) Adverse events caused by Anti-platelet Medications

6.2 Other Evaluation Items

Other evaluation items will be per standard drug eluting studies.

7. DATA ANALYSIS

7.1 Angiographic Core-Lab

Angiographic data at the index procedure and 8 months follow-up will be analyzed by Core-lab for lesion characteristics and coronary quantitative analysis.

7.2 Independent Review of Adverse Events

Objective review of adverse events (Stent Thrombosis, Cardiac Death, Myocardial Infarction, and TLR/TVR) will be conducted by a third party (medical professional) up to 3 years post index procedure. These events will be reviewed based on ARC definition. QCA results from angiographic core-lab will be provided to the reviewer as necessary.

7.3 Analysis of Results

Collected data will be analyzed and Annual Report will be submitted according to "Survey Report on new medical device usage" (Japan Pharmaceutical and Food Safety Bureau Notice 1224, no. 4, dated December 24, 2010). Subgroup analyses will be conducted as necessary to evaluate safety and efficacy of the device, and included in the resubmission report.