

PLATINUM Global Clinical Program

PROMUS™ Element™ Everolimus-Eluting Coronary Stent System



STUDY OBJECTIVE

The PLATINUM program is designed to evaluate the safety and effectiveness of the PROMUS™ Element™ Everolimus-Eluting Coronary Stent System for the treatment of up to two *de novo* atherosclerotic coronary lesions.

UP TO 160 CLINICAL SITES

- Asia Pacific
- Europe
- Japan
- United States



PROGRAM DESIGN

Workhorse (WH) Randomized Controlled Trial (RCT) (N=1,532)

- Global, multicenter, prospective, single-blind, randomized (1:1) non-inferiority trial comparing the PROMUS™ Element™ Stent to the XIENCE V™ (PROMUS™) Stent in lesions ≤ 24 mm in length with reference vessel diameters (RVD) ≥ 2.50 mm to ≤ 4.25 mm.

Small Vessel (SV) Subtrial (≥ 2.25 mm to < 2.50 mm) (N=94)

- Global, multicenter single arm subtrials comparing the 12-month TLF rate for the PROMUS™ Element™ Stent (test) group to a pre-specified performance goal. The performance goal is based on historical TAXUS™ Express™ Stent results.

Long Lesion (LL) Subtrial (> 24 mm and ≤ 34 mm) (N=102)

- Global, multicenter single arm subtrials comparing the 12-month TLF rate for the PROMUS™ Element™ Stent (test) group to a pre-specified performance goal. The performance goal is based on historical TAXUS™ Express™ Stent results.

Pharmacokinetics Subtrial (N=20-30)

Quantitative Coronary Angiography/IVUS Trial (N=100)

PLATINUM Global Clinical Program

PROMUS™ Element™ Everolimus-Eluting Coronary Stent System

CLINICAL ENDPOINTS

- Primary endpoint for WH RCT, SV and LL: 12-month target lesion failure (TLF).
- TLF is defined as any ischemia-driven target lesion revascularization (TLR) or myocardial infarction (Q-wave and non-Q-wave)/cardiac death related to the target vessel.
- WH RCT, SV and LL clinical follow-up at 30 days, 6, 12, 18 months, 2, 3, 4 and 5 years.
- Expected 12-month primary endpoint data release, American College of Cardiology 2011.

Quantitative Coronary Angiography (N=100)

- Primary Endpoint: Composite rate of the following cardiac events at 30 days post-index procedure:
 - Myocardial infarction (Q-wave and non-Q-wave)
 - Cardiac death
 - Target lesion revascularization (TLR)
 - Stent thrombosis (ST)
(definite or probable by Academic Research Consortium [ARC] definitions)

Efficacy Endpoints

- 9-month in-stent late loss and post-procedure incomplete apposition

**Boston
Scientific**

Delivering what's next.™

www.bostonscientific-international.com

To date (August 2009)

©2009 Boston Scientific. All Rights Reserved.

PROMUS™ Element™ Everolimus-Eluting Coronary Stent System is CE mark pending, not available for sale in the European Economic Area (EEA). The PROMUS Stent is a private-labeled XIENCE V Everolimus-Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific. XIENCE V is a trademark of Abbott Laboratories group of companies.

All cited trademarks are the property of their respective owners. CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for the use only in countries with applicable health authority product registrations.

PSST 5606 Printed in Germany by medicalvision.

RCS Nanterre B420 668 420

© 2009 Boston Scientific Corporation
or its affiliates. All rights reserved.
DINCAR2496EA