

# PERSEUS Clinical Program

TAXUS™ Element™ Paclitaxel-Eluting Coronary Stent System

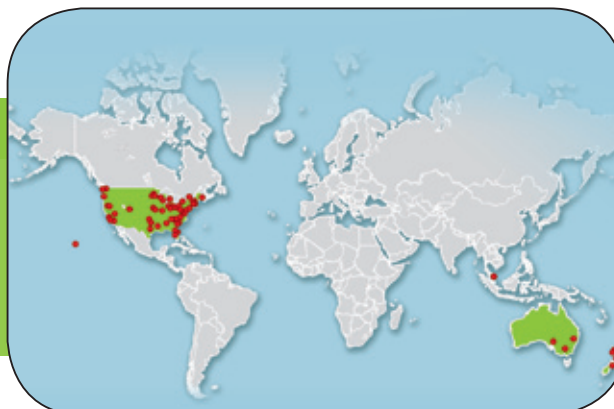
## PROGRAM OBJECTIVE

The PERSEUS Clinical Program is designed to evaluate the safety and efficacy of Boston Scientific's TAXUS™ Element™ Paclitaxel-Eluting Coronary Stent.



## 90 CLINICAL SITES

- United States (82 WH & 28 SV)
- Australia (3 WH)
- New Zealand (4 WH)
- Singapore (1 WH)



## TRIAL DESIGN

### Workhorse (WH 2.75, 3.00, 3.50, 4.00 mm) (N=1,264)

- Global, multicenter, prospective, 3:1 randomization, single-blind, non-inferiority trial comparing the TAXUS™ Element™ Stent to the TAXUS™ Express™ Stent in *de novo* lesions up to 28 mm in length and reference vessel diameters  $\geq 2.75$  mm to  $\leq 4.00$  mm.
- Enrollment completed October 2008.

### Small Vessel (SV 2.25, 2.50mm) (N=224)

- Multicenter, single-arm superiority trial comparing the TAXUS™ Element™ Stent to the Express™ Stent (historic control from the TAXUS V trial) in *de novo* lesions up to 20 mm in length and reference vessel diameters  $\geq 2.25$  to  $< 2.75$  mm.
- Enrollment completed August 2008.

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## CLINICAL ENDPOINTS

### Workhorse

- Primary endpoint: 12-month target lesion failure (TLF).  
TLF is comprised of any ischemia-driven target lesion revascularization, myocardial infarction (Q-wave and non Q-wave) or cardiac death related to the target vessel.
- Secondary endpoint: 9-month In-segment percent diameter stenosis (%DS) measured by quantitative coronary angiography.
- Quantitative coronary angiography follow-up at 9 months (N=330).
- Clinical endpoints measured in-hospital and at 30 days, 9, 12, 18 months and 2, 3, 4 and 5 years.
- Expected primary endpoint data release, American College of Cardiology 2010.

### Small Vessel

- Primary endpoint: 9-month in-stent late loss.
- Secondary endpoint: 12-month TLF.
- Quantitative coronary angiography follow-up at 9 months (N=224).
- Clinical endpoints measured in-hospital and at 30 days, 9, 12, 18 months and 2, 3, 4 and 5 years.
- Expected primary endpoint data release, American College of Cardiology 2010.

### Diabetic Enrollment<sup>1</sup>

- Workhorse N=261 minimum, 350 maximum
- Small Vessel N=40 minimum, 95 maximum

**Boston  
Scientific**

*Delivering what's next.™*

<sup>1</sup> Diabetes equals all medically-treated diabetes

To date (August 2009)

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