2 YEAR CLINICAL OUTCOMES FROM THE PIVOTAL RESOLUTE US STUDY

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Background: The Resolute zotarolimus-eluting stent (R-ZES) was developed to allow sustained release of zotarolimus to inhibit neointimal hyperplasia after treatment of coronary stenosis, while preserving efficacy. R-ZES has been prospectively studied in 5130 patients enrolled in 5 trials of the RESOLUTE Global Clinical Program (RESOLUTE First-in-Man; All Comers [RAC]; International [RINT]; Japan and US), all with similar endpoint definition and adjudication. RAC was a randomized trial demonstrating non-inferiority of the R-ZES in comparison to the control everolimus-eluting stent. The RESOLUTE US (RUS) trial provides a larger cohort of subjects treated with R-ZES specifically with indications under consideration for FDA approval, and consists of a large Main Study cohort and 2 smaller studies of 2.25 and 4.0 mm stent sizes, and is currently in long term follow-up.

Methods: The RUS Main Study compares R-ZES patients with patient level data from the Endeavor zotarolimus-eluting stent program using similar inclusion criteria and propensity scores to adjust for possible differences in patient and lesion characteristics, and the 2.25 and 4.0 studies compare with prespecified performance goals. Patients with ≤2 de novo lesions in native coronary arteries with an RVD between 2.25 and 4.0 mm were included; patients with acute MI were excluded. The Main Study primary endpoint was target lesion failure (TLF; cardiac death, target vessel MI, and clinically driven TLR) at 1-year.

Results: A total of 1402 patients were enrolled at 116 US investigational centers with the following clinical demographics; mean age, 64.1 yrs; 68.3% male; 34.4% diabetics; and 31.8% unstable angina. The primary endpoint of target lesion failure at 1 year for the Main Study cohort was 3.7%, and ARC definite or probable stent thrombosis was 0.1%, meeting the comparison for non-inferiority as presented at ACC 2011.

Conclusions: The RESOLUTE US study evaluated US patients to support the FDA evaluation of the R-ZES. Two-year clinical outcomes in the Main Study and the 2.25 and 4.0mm studies will be presented at ACC 2012.