Primary Endpoint Results of the TAXUS Liberté Post-Approval Study

**TCT-167**

**Primary Endpoint** Results of the TAXUS Liberté Post-Approval Study

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**Background:** The TAXUS Liberté Post-Approval Study (TL-PAS) is a prospective, multicenter US registry which enrolled 4119 patients, of which 1592 were defined as “on-label”, i.e. treated as per the FDA-approved labeling for TL. Unique features of this registry include the TL stent and exclusive use of at least 12 months of prasugrel as part of a dual antiplatelet therapy (DAPT) strategy after stenting. Previous work demonstrated that in-hospital major adverse cardiac events (MACE) were favorable when compared to the TAXUS Express ARRIVE registries, which utilized the TAXUS Express (TE) stent and clopidogrel.

**Methods:** Patients were enrolled at 82 sites between December 2009 - January 2012. After stenting, patients were prescribed aspirin and prasugrel (5 mg or 10 mg doses, as appropriate) for 12 months. Statistical testing was performed to determine if the primary endpoint of 12-month cardiac death or MI for the TL stent was non-inferior to the TE stent. A total of 2463 “on-label” patients receiving the TL stent from the TL-PAS (n=1592) and TAXUS ATLAS Workhorse studies (WI; n=871) were compared to the 3676 “on-label” TE-treated patients in the control arm of TAXUS ATLAS WI (n=978) and ARRIVE II registries (n=2698). Secondary outcomes including MACE (death, MI or target vessel failure), stent thrombosis and GUSTO moderate/severe bleeding are reported in the overall and “on-label” populations of TL-PAS.

**Results:** Rates of the primary endpoint of cardiac death or MI were 3.0% (108/3554) with TE and 2.2% (52/2384) with TL; thus the criteria for non-inferiority were met (p<0.0001). Low rates of other adverse cardiac outcomes and bleeding were observed (Table) and were lower in the on-label group.

**Conclusions:** The 1 year TL-PAS primary endpoint results show low rates of cardiac death/MI (as well as overall MACE, stent thrombosis, and bleeding) utilizing a strategy of TAXUS Liberté stent and DAPT including prasugrel.

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**Benefit of Large Size Bare Metal Stent in Long Term Observation of Real World Large Population**

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**Background:** Drug eluting stent (DES) has been vastly used for percutaneous coronary intervention (PCI), but its late restenosis has been reported and long term benefit has been questionable especially in large size stent.

**Methods:** Consecutive 12276 patients who received PCI between 2004 and 2011 were included in the study. Patients were divided into 4 groups: small bare metal stent (BMS), large BMS, small and large DES group depending on kind and size of implanted stents. Small stent was defined as its size was 3.25mm or smaller. Large stent was defined as the others. Selection of each stent was decided by operators. Average observation period was 1488 days. Shortest and longest observation periods were 1 and 2647 days. All-cause mortality and target lesion revascularization (TLR) rate was compared. Hazard ratio (HR) of morality and TLR in small DES and large BMS compared to small BMS, and in large DES compared to large BMS and its 95% confidence intervals (CIs) were calculated with multivariate Cox regression analysis adjusted for patient background.

**Results:** 522, 2096, 3328 and 394 patients were included in small BMS, small DES, large BMS and large DES group. Mortality was observed in each group was 475 (7.2%), 128 (6.1%), 202 (6.1%) and 23 (5.8%) patients. TLR was observed in 332 (5.1%), 112 (5.3%), 134 (4.0%) and 32 (8.1%) patients. HRs of mortality compared to small BMS in small DES, large BMS and large DES were 0.99 (95 CI: 0.80-1.02, p = 0.92), 0.65 (95 CI: 0.70-1.01, p = 0.068) and 0.80 (95 CI: 0.48-1.33, p = 0.39). HR of mortality in DES compared to large BMS was 1.01 (95 CI: 0.60-1.72, p = 0.97). HRs of TLR compared to small BMS in small DES, large BMS and large DES were 1.04 (95 CI: 0.83-1.29, p = 0.75), 0.72 (95 CI: 0.59-0.88, p = 0.002), and 1.40 (95 CI: 0.97-2.03, p = 0.070). HR of TLR compared to large BMS in large DES was 1.83 (95 CI: 1.24-2.70, p = 0.002).

**Conclusions:** No significant difference was observed in mortality. Large BMS significantly reduced TLR compared to small BMS. Large DES significantly increased TLR compared to large BMS. Large BMS showed lowest TLR rate among all groups tested.

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**BioFLOW-III an all comers registry with a Sirolimus Eluting Stent, Presentation of One Year Target Lesion Failure Data**

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**Background:** The aim of this registry is to evaluate the clinical performance of a new generation Sirolimus eluting stent system (Osiro) in a large patient population in standard clinical care. The Osiro is a unique hybrid solution that combines passive and active components. PROBIO passive coating encapsulates the stent and minimizes interaction between the metal stent and surrounding tissue. BIOlute active coating contains a highly biocompatible and biodegradable polymer.

**Methods:** Between August 2011 and March 2012, 1,356 subjects were enrolled consecutively in this international, multicentric BIOFLOW-III all-comers registry using the Osiro Sirolimus eluting stent. Primary endpoint is Target Lesion Failure (TLF) at twelve months follow-up. Pre-specified subgroups were diabetes, DM type 1, type 2, smoking status, hypertension, hypercholesteremia, diabetes, obesity, hypertension, hypercholesteremia, diabetes and obesity. Osiro hybrid stent system was evaluated against large BMS in large DES was 1.04 (95% CI: 0.83-1.29, p = 0.75) compared to small BMS in large DES, large BMS and large DES were 0.99 (95% CI: 0.80-1.02, p = 0.92), 0.80 (95% CI: 0.70-1.01, p = 0.068) and 0.80 (95% CI: 0.48-1.33, p = 0.39). HR of mortality in DES compared to large BMS was 1.01 (95% CI: 0.60-1.72, p = 0.97). HRs of TLR compared to small BMS in small DES, large BMS and large DES were 1.04 (95% CI: 0.83-1.29, p = 0.75), 0.72 (95% CI: 0.59-0.88, p = 0.002), and 1.40 (95% CI: 0.97-2.03, p = 0.070). HR of TLR compared to large BMS in large DES was 1.83 (95% CI: 1.24-2.70, p = 0.002).

**Results:** Nine hundred seventy one men (72%) and three hundred eighty three women (28%) were included in the study. Patients range from 29-91 years. Based on our preliminary data, the majority of subjects presented with diabetes 30% 48% of all stented vessels had a diameter ≤2.75mm, 4% presented with chronic total occlusion. Eleven percent of the subjects experienced unstable angina, 47% stable angina. Acute MI was seen in 33% of the subjects (NSTE MI 22%, STEMI 11%). The portion of elderly subjects (≥ 75 years) is represented by 25%. Ninety seven percent (1,321) follow up compliance at six months and ninety five percent (1,289) at twelve months were achieved. An unbiased patient population was seen in the registry with more than 52% type B2/C lesions. Moderate and severe calcification was observed in 31%. The Osiro hybrid stent system demonstrated excellent device (98.7%) and procedure success (98.2%). In this