TCT-30
Abstract Withdrawn

Bioabsorbable Vascular Scaffolds
Moscone West, 3rd Floor, Room 3018
Tuesday, October 29, 2013, 1:00 PM–3:15 PM
Abstract nos: 31-39

TCT-31
ABSORB EXTEND: An Interim Report on the 24-month Clinical Outcomes from the First 250 Patients Enrolled
Robert J. Whitbourn, MD
St. Vincent Hospital Melbourne, Melbourne, Australia

Background: The safety and performance of the Absorb Bioresorbable Vascular Scaffold (Absorb BVS) (Abbott Vascular, Santa Clara, CA) has been previously established in 131 patients from Cohort A and Cohort B of the First-in-Man ABSORB trial. Results out to 3 years have been presented in 100 patients from the ABSORB Cohort B trial. At 36 months, the MACE rate was 10.0%, with no scaffold thrombosis reported. ABSORB EXTEND was initiated as a global continued access study (outside of the US) to expand experience with the Absorb BVS to different geographies. Additionally, patients were treated for longer coronary lesions than those in the ABSORB trial using either longer scaffold lengths or planned overlap of the Absorb BVS.

Methods: ABSORB EXTEND is a prospective, single-arm, open-label clinical study that will enroll approximately 800 patients at up to 100 sites. Included are patients with lesions ≤ 28 mm in length and reference vessel diameter of 2.0 - 3.8 mm (as assessed by on-line QCA or IVUS). Treatment of a maximum of two de novo native coronary artery lesions, each in a different epicardial vessel, is permitted.

Results: Interim 12-month data in the first 250 ABSORB EXTEND study patients have been previously presented. Patients included 35% with unstable angina, 29% with prior MI and 25% with diabetes mellitus. The mean RVD was 2.58 mm and mean lesion length was 11.7 mm. In these 250 patients, the MACE and TFV rates were 4.4% and 4.8% respectively. Long-term, 24-month follow-up data will be available for these patients in October 2013 and will provide substantial data on the long-term safety and performance of the Absorb BVS in a larger population of patients, including those with planned overlapping and dual vessel treatment. Clinical composites and component end points will be presented out to 24 months.

Conclusions: Long-term outcomes in approximately 250 patients at 24 months (the largest patient cohort reported at this time point to date) from ABSORB EXTEND will provide further insight into the safety and efficacy of the Absorb BVS in patients with longer lesions.

TCT-32
First Report of the Four Year Clinical Results of the ABSORB Trial Evaluating the Absorb Everolimus Eluting Bioresorbable Vascular Scaffold in the Treatment of Patients with de Novo Native Coronary Artery Lesions
Bernard Chevalier, MD
ICPS, Massy, France

Background: The ABSORB Cohort A trial results demonstrated the safety of Absorb BVS (Abbott Vascular, Santa Clara, CA, USA) in 30 patients with single de novo native coronary artery lesions, with a low long-term MACE rate at 5 years (3.4%) and no scaffold thrombosis. The ABSORB Cohort B trial, a continuation of that assessment with a modified Absorb BVS, enrolled 101 patients at 12 sites in European and Asia Pacific regions in 2009.

Methods: The patients of the ABSORB Cohort B trial were divided into 2 groups. Cohort B1 (45 patients) having imaging follow-up performed at 180 days and 2 years and Cohort B2 (56 patients) having imaging follow-up performed at 1 and 3 years. Key clinical endpoints include scaffold thrombosis, ischemia driven MACE (ID-MACE) of its components at 30 days, 6, 9 and 18 months, and 1, 2, 3, 4 and 5 years.

Results: In the ABSORB Cohort B trial, the mean age was 62 years, 72% of patients were male, 17% of patients were current tobacco users. Patients with diabetes: 17%, hypertension: 66%, hypercholesterolemia: 85%, family history of CAD: 55%, stable angina: 68%, of which 1.8% having stable angina with CCS classiﬁcation of III or IV. Patients with unstable angina: 15%, 2% with unstable angina of Braunwald Class III. Lesion location was RCA (33%), LAD (43%), LCX (22%) and Ramus (1%), with ACC/AHA lesion classiﬁcation of A for 1% of patients, B1 for 55%, B2 for 40% and C for 4%. Clinical data up to 3 years showed an ID-MACE rate of 10.0% with no events of scaffold thrombosis. Late loss at 3 years was 0.29 ± 0.43mm. Quantitative IVUS results revealed mean scaffold area and mean lumen area enlargement between baseline and 3 years. The scaffold enlargement at 3 years was conﬁrmed by OCT. Furthermore, OCT results confirmed earlier pre-clinical data showing that the scaffold is resorbed by 3 years. Overall, clinical outcomes from the ABSORB Cohort B Trial (Groups 1 and 2) confirm the performance and safety of the Absorb BVS out to 3 years.

Conclusions: Four-year data are currently being collected. The long-term 4-year clinical results for Cohort B1 will be presented and will provide further insight into the longer-term safety and efficacy of the Absorb BVS.