Brief Summary of the Circulatory System Devices Panel Meeting – March 15, 2016

The Absorb GT1™ Bioresorbable Vascular Scaffold (BVS) System

Introduction:

The Circulatory System Devices Panel of the Medical Devices Advisory Committee to the Food and Drug Administration met on March 15, 2016, to discuss, make recommendations, and vote on information related to the premarket approval application for the Absorb GT1™ Bioresorbable Vascular Scaffold (BVS) System sponsored by Abbott Vascular.

The sponsor has proposed the following Indications for Use:

The Absorb GT1 BVS is a temporary scaffold that will fully resorb over time and is indicated for improving coronary luminal diameter in patients with ischemic heart disease due to *de novo* native coronary artery lesions (length ≤ 24 millimeters mm) with a reference vessel diameter of ≥ 2.5 mm and ≤ 3.75 mm.

Panel Deliberations/FDA Questions:

Question 1: Clinical Non-Inferiority of the BVS as compared to XIENCE stent

The consensus opinion was that the 1-year results of the ABSORB III Randomized Clinical Trial demonstrated adequate evidence of clinical non-inferiority of the BVS as compared to the XIENCE stent with regard to safety and effectiveness in the patient population described by the proposed indications for use. There were some concerns about trends in the event rates that were higher in the BVS treatment group for the components of the primary endpoint (target lesion failure: cardiac death, target vessel myocardial infarction and ischemia-driven target lesion revascularization) and device thrombosis.

Question 2: Event Rates in Small Vessels

There was uniform agreement amongst panel members that the increased safety event rates were concerning when the BVS is used in small vessels (< 2.25 mm by Quantitative Coronary Angiography).

Question 3: Labeling – Use in Small Vessels

With respect to the proposed precaution statement, the panel believed it is important to choose the appropriate target vessels for BVS implantation, and operators should utilize additional imaging techniques when the visual estimation of the target vessel size is ≤ 3.0 mm. The panel agreed with the sponsor's proposed warning.

Question 4: Labeling – Subjects with Diabetes Mellitus

The panel agreed that language should be added to the small vessel warning to alert operators of the particularly high rate of adverse events in patients with diabetes mellitus with small vessels.

Question 5: Duration of Follow-up

The panel agreed that the amount of available follow-up data provided was sufficient to evaluate safety and effectiveness.

Question 6: Post-dilatation

The panel agreed that the proposed precaution regarding post-dilatation at high pressure with a noncompliant balloon was acceptable as written, with reference to labeling instructions regarding the maximum recommended balloon size.

Question 7: Post-Approval Commitments

The panel agreed with the sponsor's proposed post-approval commitments and endorsed the proposal for product roll-out and operator education and training. They also made recommendations on collecting information on patient sub-groups that should be evaluated, including younger patients, women, racial and ethnic minorities. Additionally, the panel recommended evaluating the association between dual antiplatelet therapy duration and clinical outcomes.

Question 8: Labeling

The panel expressed no additional concerns with the proposed labeling. Suggestions were made regarding potential additional labeling elements that should be included regarding clinically important populations where the safety and effectiveness of BVS use has not been established (e.g., chronic total occlusions, bifurcations, ostial lesions, and acute myocardial infarction).

Vote:

The panel voted on the safety, effectiveness, and benefit-risk profile of the Absorb GT1™ Bioresorbable Vascular Scaffold (BVS) System.

On Question 1, the panel voted 9-1 that there is reasonable assurance that the Absorb GT1™ Bioresorbable Vascular Scaffold (BVS) System is safe for use in patients who meet the criteria specified in the proposed indication.

On Question 2, the panel voted 10-0 that there is reasonable assurance that the Absorb GT1™ Bioresorbable Vascular Scaffold (BVS) System is effective for use in patients who meet the criteria specified in the proposed indication.

On Question 3, the panel voted 9-0 (with one abstention) that the benefits of the Absorb GT1™ Bioresorbable Vascular Scaffold (BVS) System outweigh the risks for use in patients who meet the criteria specified in the proposed indication.

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