Data On Absorb Bioresorbable Stent Show Comparable Outcomes To Leading Drug-Eluting Stent Between One And Two Years

- Results emphasize importance of proper vessel sizing and following current instructions for use for optimal clinical outcomes

WASHINGTON, March 18, 2017 — Abbott today announced that data from the ABSORB III U.S. pivotal trial showed that Absorb, Abbott's first-of-its-kind dissolving stent, had comparable efficacy and safety results to XIENCE, Abbott's leading metallic drug-eluting stent, between one and two years after implantation. The data were presented during a late-breaking clinical trials session at the American College of Cardiology's 66th Annual Scientific Session.

The ABSORB III trial results showed no statistically significant difference in incremental rates of target lesion failure (TLF) and stent thrombosis (ST) between one and two years for Absorb versus XIENCE. TLF for Absorb was 3.7 percent vs 2.5 percent for XIENCE (p=0.18); ST was 0.3 percent for Absorb vs 0.0 percent for XIENCE (p=0.31).

Cumulative two-year TLF rates were higher with Absorb than XIENCE, particularly when the device was implanted in small vessels, which occurred in 19 percent of patients in the study. TLF was 11.0 percent for Absorb vs 7.9 percent for XIENCE (p=0.03). However, when implanted in appropriately-sized vessels, the difference was smaller and not statistically significant at 9.4 percent for Absorb vs 7.0 percent for XIENCE (p=0.11).

When pre- and post-dilatation techniques were used in addition to appropriate vessel sizing, the results for TLF and stent thrombosis were improved even further at 8.7 percent for Absorb vs 8.2 percent for XIENCE (p=0.84), demonstrating the devices had similar outcomes.

The ABSORB III study began in 2012, and since then, training on the device has evolved based on learnings in the medical community and physician experience. When Absorb was approved by the U.S. Food and Drug Administration in July 2016, the instructions for use specified the avoidance of very small vessels and included optimal implantation guidelines.

An ongoing study, called ABSORB IV started after implantation technique had evolved. A preliminary analysis of pooled rates (combined for both Absorb and XIENCE because the study is not yet unblinded) showed stent thrombosis rates of 0.4 percent at 30 days (N=2397) and 0.5 percent at 1 year (N=1415), which were less than half of the ST rates observed in ABSORB III (0.9 percent at 30 days and 1.1 percent at one year). ABSORB IV is expected to enroll a total of 3,000 patients.

"When implanted in appropriate vessel sizes and following current instructions for use, the results for Absorb are comparable to XIENCE, the gold standard drug-eluting stent, with the added feature of leaving no metal behind once it dissolves," said Charles Simonton, M.D., FACC, FSCAI, chief medical officer and divisional vice president of medical affairs for Abbott's vascular business. "We look forward to data early next year from the ABSORB IV trial, which best represents current implantation technique."

One-year results from ABSORB III were presented in October 2015, and showed comparable outcomes between Absorb and XIENCE for the study's primary endpoint of target lesion failure, which were the basis for the U.S. FDA approval in July 2016.

Abbott has emphasized implant techniques for Absorb in a training program for physicians globally. In the U.S., Abbott requires physicians to undergo comprehensive training before they are able to implant Absorb.

As part of a recent letter to healthcare providers, the FDA emphasized the importance of following instructions for target vessel selection as outlined in the product label, and recommended that physicians use optimal methods when implanting Absorb.

More information about Absorb including important safety information is available at Absorb.com.

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