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FDA Approves First Absorbable Cardiac Stent

The US Food and Drug Administration (FDA) has approved the *Absorb* GT1 Bioresorbable Vascular System (Abbott Vascular), with the first absorbable stent for coronary artery disease.

Nine members of the Circulatory System Devices panel vs 1 voted that it was safe, and 9 to 1 voted that it had an acceptable risk/benefit profile. In addition, all 10 members voted that it was effective.

The approval was based on the ABSORB III trial of more than 2000 patients randomly assigned to the Absorb GT1 or a conventional everolimus-eluting cobalt-chromium stent (*Xience*, Abbott Vascular).

The findings, which were first presented at the Transcatheter Cardiovascular Therapeutics (TCT) 2015 meeting, showed that the two devices had a clinically similar rate of target lesion failure (a composite of cardiac death, target vessel myocardial infarction, or target lesion revascularization) at 1 year (7.8% vs 6.1%, respectively). Also not significant was the between-group difference in rates of device thrombosis (1.5% vs 0.7%).

The FDA noted that potential treatment-related adverse events from the Absorb GT1 include allergic reactions, infection at the insertion site, internal bleeding, and other "coronary artery complications."

Still, today's approval "offers a new treatment option for individuals who are candidates for angioplasty but would prefer an absorbable device rather than a permanent metallic coronary stent," Dr Bram Zuckerman (Center for Devices and Radiological Health, FDA) said in the agency's release.

Within about 3 years, the poly(L-lactide) stent is completely absorbed into the body.

In its own release, Abbott noted that the device is currently available in more than 100 countries. Their plan for the United States is to offer it first to the interventional cardiology centers that participated in its clinical trials, and then to other hospitals.

Source; Abbott

Image credit;

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