

MIV Therapeutics CEO discusses role of second-generation DES

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Mark Landy, MD, CEO of MIV Therapeutics, discussed the potential for the company's second-generation VESTAsync drug-eluting stent (DES), the impressive nine-month preliminary results of its first human trial and the emerging position for second-generation stents in the field of interventional cardiology with regards to stricter FDA guidance, with *Cardiovascular Business News*.

During ACC08, Jose Costa, MD, from the Institute Dante Pazzanese of Cardiology in Sao Paulo, Brazil, presented [nine-month follow-up](#) intravascular ultrasound data for 11 patients, who demonstrated a volumetric obstruction of 3.8 percent vs. 2.8 percent at four months. Overall, the Brazilian researchers, along with respected interventionalist Alexandre Abizaid, MD, affirmed that VESTAsync has the potential for superior safety and equivalent efficacy when compared to currently available DES.

VESTAsync is coated with a polymer-free nanoscale microporous hydroxyapatite. The VESTAsync drug-delivery system is a combination of hydroxyapatite, as well as a drug formation that is loaded into the hydroxyapatite. "With this system, we actually came up with a drug-delivery coating that 0.6 of micron thick versus the other DES that are anywhere from 5 microns to 15 microns thick," Landy noted.

He said that the coating is "extremely flexible along with the benefits of being thin, which makes our DES more user-friendly and deliverable than those on the market."

Landy also highlighted that MIV's stent is "a totally polymer-free system, made from products that occur naturally, which is a much more biocompatible system." As a result, in the animal model, MIV reported more complete healing at 28 days, with a lot less inflammation.

Landy highlighted that the most recent results of the preliminary data presented at ACC is promising because "we have achieved a DES with significantly less drug, and no polymer."

"Another remarkable aspect of the study is that the patients only took Plavix for about four to five months [after PCI]. When we reported our nine-month data, all of our patients had been off-Plavix for at least four months, and we saw no untoward effects," Landy said.

Patients were only administered the dual-antiplatelet therapy for four to five months, and have only maintained their aspirin therapy to date, even as they approach their one-year clinical follow-up, he added.

MIV has not yet released where or when its larger trial will take place, even though they have confirmed that the company will extend their clinical follow-up with the current patient population up to two years. Last year at TCT, Abizaid said that the company was arranging a larger study of approximately 100 patients.

Landy said that while MIV seems to be following the appropriate trek for DES approval, a recent FDA guidance issued on March 26 and is currently open for public comments and therefore subject to change, suggests a more arduous process for such second-generation DES, which will eventually seek FDA approval.

Landy said that two aspects of the current document that could potentially affect MIV.

One aspect is that a large portion of the patient population will need to have two-year follow-up. However, Landy pointed out that the document, in its current form, does not stipulate that the follow-up must occur in the U.S. “We have been planning all along to make sure our global patient population can be pooled in the analysis,” he said.

A second aspect is that companies will now have to have more expectations during the time of a company’s investigational device exemption (IDE) application meeting, compared to the same standards currently expected during the later pre-market approval (PMA) meeting. “This process might be more cumbersome,” he added.

Overall, Landy said that the new guidance “will just a put a little more burden on companies to have a better understanding of the clinical and regulatory process.” He noted that MIV has been in the developmental and clinical trialing process for seven years.

“We are essentially the only company that has been able to achieve these goals with a polymer-free system over the last four to five years,” Landy concluded.

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