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MIV's VestaSync Polymer-Free DES Demonstrates Safety and Efficacy

MIV Therapeutics, Inc. (Atlanta, GA) announced that the 9-month data for a first-in-man clinical pilot study of its VestaSync polymer-free nanoscale microporous hydroxyapatite drug-eluting stent (DES) will be presented at the Innovative and Emerging Technologies session at EuroPCR08 in Barcelona on May 15. The preliminary 9-month data was first presented in March at the American College of Cardiology's (ACC) annual scientific sessions in Chicago. MIV's technology will also be featured at EuroPCR in "Glimpse Into the Future: New DESs," a session of live cases and presentations co-chaired by Patrick W. Serruys, MD, and Andrea Abizaid, MD. The company announced it will be commencing a larger trial in the second quarter of 2008 to further study the safety and efficacy of its VestaSync and its value as a short-term anticoagulant therapy.

The company stated that at the ACC meeting on March 31, José Costa, MD, presented the preliminary 9-month data and concluded that the VestaSync stent demonstrated excellent efficacy and safety. The presentation included 9-month follow-up intravascular ultrasound data for 11 patients who showed a volumetric obstruction of 3.8% (+/-2.3%) versus 2.8% (+/-2.2%) at 4 months. Quantitative coronary angiography of 12 patients at 9 months found a late-lumen loss of 0.37 mm (+/-0.24) versus .31 mm (+/-0.26) at 4 months. The study concluded that there was no significant difference between the 4-month and 9-month results and that the observed degradation was uniform across all patients with no outliers. No late acquired incomplete stent apposition, stent thrombosis, or major adverse coronary events were reported by Dr. Costa, the company stated.

"The data compare favorably with first-in-man data of DESs available in the US and abroad," commented Dr. Costa. "But what is more remarkable is these results were obtained with 60% less drug delivered from an ultrathin 0.6-micron coating that is entirely polymer-free."