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Two-year results from the LEADERS FREE trial presented

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The two-year results from LEADERS FREE, the first randomized clinical trial dedicated to high bleeding risk patients treated with one month of dual antiplatelet therapy (DAPT), found that a polymer-free drug-coated stent (DCS) remained both significantly safer and more effective than the comparator bare-metal stent (BMS) used in the trial.

Findings were reported today at the 28th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. Sponsored by the Cardiovascular Research Foundation (CRF), TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine. The study was also simultaneously published in *The Journal of the American College of Cardiology* (*JACC*).

Patients with a high bleeding risk (HBR) comprise approximately 20% of patients treated by PCI, yet they are usually excluded from trials of devices and antithrombotic drug regimen. Current recommendations for high-risk patients are one month of DAPT after BMS implantation and a "shortened" DAPT regimen after DES (however, usually a minimum 3-6 months). LEADERS FREE examined the use of one month of DAPT for both types of stents, specifically studying the BioFreedom DCS, which releases biolimus A9 into the vessel wall over a period of four weeks without the use of a polymer to aid drug delivery.

The prospective double-blind randomized study enrolled 2,466 patients with high bleeding risk during PCI from 68 centers in Europe, Asia and Canada. Patients were randomized (1:1) to receive a DCS (N=1,221) or

BMS (N=1,211). The primary safety endpoint was a composite of cardiac death, myocardial infarction (MI), or stent thrombosis (ST). The primary efficacy endpoint was clinically driven target-lesion revascularization (cd-TLR). The one year results were presented at last year's TCT meeting, and demonstrated superior safety and efficacy of DCS at one year.

A total of 97.7% (1,193) of DCS and 98.3% (1,191 BMS) of surviving patients had follow-up data available for analysis at two years. The primary safety endpoint at two years was 12.6% for DCS compared to 15.3% for BMS (HR 0.80; 95%CI, 0.64-0.99; P=0.039). The results for the primary efficacy endpoint of

clinically driven TLR at two years were 6.8% for DCS versus 12.0% for BMS (HR 0.54; 95%CI, 0.41-0.72; P