

Biosensors at EuroPCR, 15 - 18 May 2012

EuroPCR is Europe's leading interventional cardiovascular course. This year's congress, held in its traditional location of Paris, attracted over 11,000 delegates from around the world. Biosensors' technology featured prominently:

The primary endpoint from a physician-initiated trial, the COMFORTABLE AMI study, was presented at the *Late Breaking Trials* session by Dr. Lorenz Räber. It showed that the use of BioMatrix™ in ST-Elevated Myocardial Infarction (STEMI) patients significantly reduced the rates of major adverse cardiac events (MACE) ($p=0.004$) and demonstrated BioMatrix to be safe and effective at 12 months, compared to BMS.

New long-term data from the DIVERGE study, presented during an abstract session, showed that the use of Axxess™, Biosensors' self-expanding bifurcation drug-eluting stent (DES), in complex coronary bifurcation lesions resulted in low levels of both MACE and very late stent thrombosis (VLST) over a four-year period. According to Principal Investigator Dr. Stefan Verheye, "the four-year results confirm the earlier results already presented, and strengthen the evidence that the Axxess stent is a safe and effective alternative for patients with certain bifurcation lesions."

In addition to the presentation of new data, two announcements of major new studies involving Biosensors stents were made during the *Future and Ongoing Trials* session:

Professor Patrick Serruys announced that BioMatrix Flex™ had been chosen as the stent system for use in GLOBAL LEADERS, the largest ever randomized clinical trial involving a DES. GLOBAL LEADERS, a physician-initiated trial supported by both Biosensors and AstraZeneca, aims to enroll around 16,000 patients from an "all-comers" population to assess the potential benefits of a new antiplatelet regimen. According to Prof Serruys, BioMatrix Flex was chosen on the basis of data from the LEADERS study, reinforced by the 4-year results published in *The Lancet* in December 2011.

Dr Philip Urban announced plans for LEADERS FREE, the world's first prospective, randomised double-blind trial comparing a drug-coated stent (BioFreedom™) and a bare-metal stent (BMS). The study will involve approximately 2,500 patients identified as having a high risk of bleeding. It has been designed to assess the potential for delivering the anti-restenotic benefit associated with a DES whilst giving the shorter one-month course of dual anti-platelet therapy (DAPT) currently only recommended for a BMS.

"The results of this study will particularly important as they may show, for the first time, that a new type of stent is more effective than a bare metal stent in a subgroup of patients not previously studied, yet just as safe", commented Dr Urban. "Furthermore, this study could potentially change clinical practice by facilitating short DAPT duration in patients who may not be suitable for longer courses".