



## Biosensors DES Demonstrates Superior Strut Coverage to Industry Leading DES

**Washington, DC, 14 October 2008** – In the first study of its kind, a new medical imaging technique showed that lesions treated with a Biosensors' biolimus drug eluting stent (DES) were more than 10 times more likely to have nearly-complete stent-strut coverage at nine months than those treated with the industry standard DES. Uncovered stent struts may disrupt blood flow within the vessel and could be a contributing factor towards stent thrombosis. The results of the Optical Coherence Tomography (OCT) sub-set analysis, comparing post-implantation tissue coverage between two drug-eluting stents (DES) in a large-scale, randomized trial, were presented yesterday at the 2008 Transcatheter Cardiovascular Therapeutics (TCT) conference in Washington, DC.

The pre-defined sub-group analysis showed lesions treated with the Biosensors biolimus-eluting stent, which uses an abluminally coated biodegradable polymer, had significantly higher rates of complete tissue coverage and lower rates of poorly apposed stent struts than the industry standard DES, Johnson & Johnson Cordis' CYPHER SELECT™ ("Cypher").

In addition to the newly released OCT sub-group data, Biosensors also released 12-month follow-up data from its landmark LEADERS trial (Limus Eluted from A Durable versus ERodable Stent coating), the first head-to-head randomized study between the two DES systems in a 'real world, all comers' population using clinical results as its primary endpoint. At 12-months, the Biosensors stent continued to show equivalent safety and efficacy as compared to the Cypher stent.

The OCT analysis, a subset of the LEADERS study, included 46 patients who underwent OCT imaging at 9-months. In total, the study examined 11,068 struts in 64 lesions. At nine months, 39.4 percent of lesions treated with Cypher had more than five percent uncovered struts, as compared with only 3.6 percent of lesions that received the Biosensors stent ( $p=0.005$ ). In addition, lesions treated with Cypher were more than 10 times more likely to have more than five percent malapposition (9.7 percent vs. 0.9 percent,  $p=0.06$ ).

Commenting on the study, lead investigator Prof. Carlo Di Mario, of London's Royal Brompton Hospital, said, "We observed a thin layer of intimal coverage, with an average thickness of approximately 50 microns, on most struts in both stents, explaining the similar efficacy in preventing restenosis, an observation supported by the 12 month results from the main study. The Biosensors stent, however, showed a significantly better level of nearly complete strut coverage, possibly due to the biodegradable polymer. The better intimal coverage achieved by the Biosensors stent at 9 months possibly anticipates a lower risk of late stent thrombosis. This needs to be confirmed by the planned long-term follow-up, lasting for as long as five years after stent implantation."

Of the 1,707 patients enrolled in the LEADERS trial, 1,666, or 97.6 percent, were included in the 12-month follow-up. The primary endpoint of the non-inferiority trial was cardiac death, myocardial infarction or clinically-indicated target vessel revascularization ("TVR") at 9-months. The 9-month results for the composite endpoint, released in September 2008, were 9.2 percent for patients who received the Biosensors stent and 10.5 percent for patients who received the Cypher stent ( $p=0.003$ ). At 12 months, the rate for the Biosensors group was 10.7 percent and 12.2 percent for the Cypher group. In terms of efficacy, the likelihood of any repeat vascularisation was 7.8 percent for patients who received the Biosensors stent and 10.1 percent for those who received Cypher.

"I am very happy with the 12-month results of the LEADERS study, which confirm the 9-month results", commented Professor Patrick Serruys, head of the interventional department at Erasmus University's Thoraxcenter in Rotterdam, The Netherlands. "The Biosensors drug eluting stent, combining the novel biolimus drug and an abluminal biodegradable polymer, is a very promising technology for our patients' long term benefit", Serruys added.

Professor Stephan Windecker, head of the department of cardiovascular diseases at the University Hospital Bern, Switzerland, and principal investigator for the LEADERS trial commented, "Since the product became commercially available earlier this year, we have had significant experience using Biosensors' drug eluting stent system, with excellent clinical outcomes and device success rates, confirming the positive results achieved with the LEADERS study. I believe that these stents represent true next generation DES technology".