

The SCAI Annual Scientific Sessions
in Partnership with **ACC i2 Summit**
March 29 - April 1, 2008 • CHICAGO



EMBARGOED FOR RELEASE
Monday, March 31, 8:00 AM CDT
Presentation Number: 2407-9

CONTACT:
Kathy Boyd David
SCAI
Cell: 717-422-1181
pr@scai.org

Amy Murphy
ACC
Direct: 202-375-6476
Cell: 240-328-4549
amurphy@acc.org

SPIRIT II EXPLORES LONG-TERM PERFORMANCE OF XIENCE V STENT

Clinical edge of everolimus-coated stent over Taxus stent uncertain at two years

CHICAGO, Ill. (March 31, 2008) — Early results of the SPIRIT II study showed that the XIENCE V stent was superior to the Taxus stent in both six-month findings on angiography and one-year clinical outcomes. Now, a new analysis shows that after two years, the investigational everolimus-coated XIENCE V stent may continue to hold a clinical edge over its paclitaxel-coated competitor, but the differences between the two are no longer statistically significant.

The two-year findings of the SPIRIT II study are being reported today in a Late-Breaking Clinical Trials session at the SCAI Annual Scientific Sessions in Partnership with ACC i2 Summit (SCAI-ACCi2) in Chicago. SCAI-ACCi2 is a scientific meeting for practicing cardiovascular interventionalists sponsored by the Society for Cardiovascular Angiography and Interventions (SCAI) in partnership with the American College of Cardiology (ACC).

Patrick W. Serruys, MD, Thoraxcenter, Erasmus Medical Center, Rotterdam, The Netherlands, led the SPIRIT II study. He and his colleagues recruited 300 patients from 28 medical centers in Europe, New Zealand and India who needed stenting of up to two new coronary lesions. Patients were randomly assigned to treatment with the XIENCE V everolimus-eluting stent or the Taxus paclitaxel-eluting stent.

The study primarily set out to document any differences in the amount of arterial tissue that grew into the stents at six months (in-stent late loss). As previously reported, the results were significantly better for the XIENCE V stent when compared to the Taxus stent. At one-year follow-up, the combined rates of major adverse cardiac events (MACE), consisting of cardiac death, heart attack and repeat procedure to treat the target lesion, were also significantly better in the XIENCE V group.

Now, new data from a late-stage evaluation report that, although the XIENCE V stent continues to show a trend toward improved clinical outcomes compared to the Taxus stent at two years, the differences

between the two stents were no longer statistically significant. The overall MACE rate at two years was 40 percent lower in patients treated with the XIENCE V stent (6.6 percent vs. 11.0 percent in the Taxus group). Repeat procedures to treat the target lesion were performed in 3.8 percent and 6.8 percent of patients, respectively, a 44 percent reduction favoring the XIENCE V stent. Similarly, the rates of heart attack were 2.8 percent and 5.5 percent, respectively, a 49 percent reduction, and the rates of cardiac death were 0.5 percent and 1.4 percent, respectively, a 64 percent reduction. There was no difference in the rates of blood clotting inside the stent, or stent thrombosis, at two years.

In the 117 patients who had follow-up angiography at two years, there was no significant difference in the rates of re-narrowing of at least 50 percent (binary restenosis) within the stents (2.1 percent with the XIENCE V stent vs. 2.9 percent with the Taxus stent). In-stent late loss was virtually identical (0.33 mm vs. 0.34 mm, on average, respectively).

Dr. Serruys will present the two-year results of the SPIRIT II study on Monday, March 31 at 8:45 a.m. CDT in the Grand Ballroom, S100.

###

About SCAI

Headquartered in Washington, DC, the Society for Cardiovascular Angiography and Interventions is a 4,000-member professional organization representing invasive and interventional cardiologists in over 60 nations. SCAI's mission is to promote excellence in invasive and interventional cardiovascular medicine through physician education and representation, and advancement of quality standards to enhance patient care. SCAI's annual meeting has become the leading venue for education, discussion, and debate about the latest developments in this dynamic medical specialty.

About ACC

The American College of Cardiology is leading the way to optimal cardiovascular care and disease prevention. The College is a 34,000-member nonprofit medical society and bestows the credential Fellow of the American College of Cardiology upon physicians who meet its stringent qualifications. The College is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research. The ACC provides professional education and operates national registries for the measurement and improvement of quality care.