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CONTACT:  
Kathy Boyd David  
SCAI  
Cell: 717-422-1181  
[pr@scai.org](mailto:pr@scai.org)

Amy Murphy  
ACC  
Direct: 202-375-6476  
Cell: 240-328-4549  
[amurphy@acc.org](mailto:amurphy@acc.org)

**INVESTIGATIONAL ANTI-RESTENOSIS DRUG PIMECROLIMUS DISAPPOINTS**  
*Novel multi-reservoir stent design still under study*

**CHICAGO, Ill. (March 31, 2008)** — A new medication that researchers had hoped would reduce the risk of arterial renarrowing after stenting has turned in a disappointing performance in a multicenter clinical trial, but the multi-reservoir stent that was used to deliver the drug is still considered promising.

Pimecrolimus, an anti-inflammatory medication, was expected to reduce arterial inflammation and, therefore, the overgrowth of scar tissue, or neointimal hyperplasia, that causes in-stent restenosis. Instead, patients treated with pimecrolimus-eluting stents fared far worse than patients treated with stents that delivered a combination of pimecrolimus and paclitaxel, or paclitaxel alone, according to the Randomized, Multi-Center Study of the Pimecrolimus-Eluting and Pimecrolimus/Paclitaxel-Eluting Coronary Stent System in Patients with De Novo Lesions of the Native Coronary Arteries (GENESIS). Paclitaxel is also an anti-restenosis medication, but it works by inhibiting cell division, rather than by reducing arterial inflammation.

The GENESIS study was terminated early by its sponsors. The data gathered to that point 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).

“Despite pre-clinical data suggesting marked efficacy of pimecrolimus in suppressing neointimal hyperplasia, the extent of tissue growth and resulting rates of target vessel revascularization at six months were high in patients treated with this drug,” said Stefan Verheye, MD, PhD, co-director of the catheterization laboratories at Antwerp Cardiovascular Center, ZNA Middelheim Hospital, Antwerp, Belgium.

The GENESIS study was also designed to a novel stent design featuring reservoirs that are filled individually with an active drug and resorbable polymer matrix. This design enables the stent to deliver more than one drug at a time from adjacent reservoirs. In the case of the GENESIS study, the Symbio stent was loaded with two medications that inhibit restenosis by two different pathways. In addition, the reservoirs limit the contact between the polymer and the artery wall.

For the study, Dr. Verheye and his colleagues enrolled 248 patients with single new coronary artery lesions, recruiting them from 18 medical centers in Europe and Israel. Patients were randomly assigned to stenting with the Corio stent, which delivers pimecrolimus; the Symbio stent, which delivers both pimecrolimus and paclitaxel; or the paclitaxel-coated CoStar stent. All of these stents are made with the reservoir design.

After nearly six months of follow-up, shrinkage of the arterial opening inside the stent (in-stent late loss) was greatest with the pimecrolimus-eluting Corio stent (1.40 mm), mid-range with the dual-drug Symbio stent (0.96 mm) and least with the paclitaxel-eluting CoStar stent (0.58 mm), but none of the differences between stents was statistically significant. Other angiographic findings followed the same pattern, including minimal lumen diameter, percent diameter stenosis and restenosis rate—as did the findings of intravascular ultrasound at six months.

At six months, 39 percent of patients treated with the Corio stent experienced a major adverse cardiac event (MACE), including a 35 percent rate of repeat procedure in the target artery. With the Symbio stent, those rates were both 14.4 percent, and with the CoStar stent, they were both 2.0 percent. The difference in MACE rates between the CoStar stent and both of the pimecrolimus stents was highly statistically significant ( $p < 0.0001$ ). The rate of stent thrombosis at six months was 2.0 percent with the Corio stent, 1.0 percent with the Symbio stent and 0 percent with the CoStar stent.

Despite the disappointing performance of pimecrolimus, the new reservoir stent design continues to undergo clinical testing with other medications. “The GENESIS trial is the first to demonstrate the feasibility of dual drug delivery from adjacent reservoirs using the reservoir technology and demonstrates the ability for both drugs to affect the tissue response to coronary intervention,” Dr. Verheye said.

*Dr. Verheye will present the results of the "Randomized, Multi-Center Study of the Pimecrolimus-Eluting and Pimecrolimus/Paclitaxel-Eluting Coronary Stent System in Patients with De Novo Lesions of the Native Coronary Arteries" (GENESIS) study on Monday, March 31 at 9:15 a.m. CDT in the Grand Ballroom, S100.*

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### **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.