Conclusions:

One with multi-organ failure post CABG, one with cardiogenic shock), placement; ten associated with MI) and 5 deaths (three associated with slant thrombosis, adjudicated by a centralized Safety Adjudication Committee.

Background: Patients treated with a sirolimus loading dose of 6 mg 4-24 hours post-PTCA, followed by 2 mg/day for 4 weeks. A 1 month course of therapy was selected because in the RAVEL trial, efficacy was demonstrated using stents that delivered sirolimus over a 4-6 week duration. For most patients, the cost of a 4-week drug regimen (about $400) was reimbursed by their insurance provider. Serum electrolytes, lipid profile, renal panel, and complete blood counts were measured at 1, 3, and 5 weeks after drug initiation. Patients are contacted monthly to determine adverse reactions, death, myocardial infarction, and need for repeat revascularization.

Results: To date, 11 patients at high risk for restenosis have been treated with oral sirolimus and patients are accruing at approximately 3/week. Indications included: failed radiation therapy + 7; lesion length too long for brachytherapy = 1; vessel diameter too small for brachytherapy = 3. The mean age was 57.6 +/- 11.8 and 63.6% were diabetic. The target lesion was the left anterior descending in 7 patients; right coronary in 0; and circumflex in 2; radial graft to LAD in 1; saphenous vein graft to obtuse marginal branch in 1. The mean number of previous restenoses per patient was 3.2 +/- 1.8. The mean time interval between the sirolimus treatment procedure and the immediately preceding revascularization procedure was 5.4 +/- 2.4 months. With very early follow-up, no adverse events have occurred.

Conclusion: Patients at extremely high risk for recurrent restenosis are receiving a 30-day course of oral sirolimus. Six-month follow-up results will be presented.