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The European RENO Registry: Results of 1,098 Patients Support Routine Use of Intracoronary Radiation For Primary Treatment of Blocked Stents

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Report by Prof. Dr. Sigmund Silber, Munich

The RENO registry trial further demonstrated that routine application of intracoronary radiation therapy, also known as vascular brachytherapy (VBT), is highly effective in the treatment of restenosis following coronary angioplasty and stent procedures. This condition affects up to 30% of the 1.5 million patients who undergo coronary interventional procedures annually worldwide.

The results, generated by the recently concluded European REgistry NOvoste (RENO) Trial, confirm data generated by previously released, placebo-controlled clinical trials. Dr. Philip Urban, Principal Investigator, presented the RENO trial results at a session of the European Society of Cardiology Congress in Stockholm, Sweden.

The RENO registry trial, which began in April 1999, included 1,098 patients from 46 hospitals throughout Europe and the Middle East. This registry trial assessed major adverse cardiac events (MACE), which include death, heart attack and the need for revascularization procedures, at 6 months following the initial radiation procedure. Approximately 78% of patients in this registry trial presented with in-stent restenosis and the remaining patients presented with de novo or restenotic lesions. This trial included diabetic patients (n=256), patients with long lesions (mean lesion length 25.9 mm, n=555) and patients with saphenous vein graft disease (n=67).

The results of the RENO registry trial demonstrated that patients receiving beta radiation exhibited a low MACE rate of 18.7% for all patients included in the study (17.7% in the in-stent restenosis group, Table 1). This compares favorably to MACE rates of 18% to 28% published in prior randomized, placebo-controlled clinical trials for those patients receiving either beta or gamma radiation to treat in-stent restenosis.

Dr. Philip Urban, Director of Interventional Cardiology at La Tour Hospital in Geneva, Switzerland, stated, "These data reflect real world clinical applications and outcomes of beta radiation for the treatment of coronary artery disease. These findings support vascular brachytherapy as the standard of care for in-stent restenosis. It is also very interesting that the results from this registry trial improve upon the established clinical efficacy of beta radiation demonstrated in other, more restrictive, clinical trial conditions. In fact, a cohort of 49 patients with long lesions (average lesion length 30.9 mm) treated with the longer 60 mm Radiation Source Train resulted in a low 8.2% target vessel revascularization (TVR) rate, further supporting the notion that increased radiation length coverage may result in more favorable clinical outcomes." TVR rate refers to the percentage of patients that require a repeat revascularization procedure.

Furthermore, a separate analysis was performed on a RENO patient subset (n=139) and compared to a placebo control group selected from the Washington Radiation for In-Stent Restenosis Trials (WRIST / LONG WRIST (n=94)). These data demonstrated a 75% reduction in TVR rate (14.9% vs. 60.6%) and a 72% reduction in MACE rate (17.9% vs. 64.9%) for the subset of patients receiving Sr-90 beta radiation compared

to this placebo control group. The average lesion length for this RENO patient subset was 35.3 mm (site reported) compared to the average lesion length of 28.0 mm in the WRIST / LONG WRIST placebo control group.

Table 1: RENO Registry Trial
Treatment group MACE rates in Vascular Brachytherapy Trials
(Follow-up time period 6 - 9 months)

Parameter	SCRIPPS	WRIST	GAMMA1	INHIBIT	START	RENO*
Patients treated with radiation						
Lesion length	26 12mm	65 27mm	131 19mm	166 17mm	244 16mm	878 19mm
MACE (placebo)	62%	68%	46%	33%	26%	-
MACE (VBT)	19%	29%	28%	22%	18%	17.7%

*RENO MACE rate in patients treated for in-stent restenosis (n=878)

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