One-Year Clinical and Angiographic Outcomes from the RESET Trial
(Randomized Evaluation of Sirolimus-eluting versus Everolimus-eluting stent Trial)

BACKGROUND: Sirolimus-eluting stent (SES) is the most widely used coronary drug-eluting stent (DES) in Japan. It has recently been reported that everolimus-eluting stent (EES) had lower rate of target-lesion revascularization and stent thrombosis at 1 year as compared with paclitaxel-eluting stent. However, trial results comparing EES with SES are largely unknown.

PURPOSE: To evaluate whether the newly-approved EES is not inferior to the SES at 1-year.

DESIGN: Interventional, randomized, safety/efficacy, open label study. Parallel assignment of 3,197 patients; EES=1,597, SES=1,600. One-year follow-up N=3,146; EES=1,565, SES=1,581.

PRIMARY ENDPOINT: Target-lesion revascularization at 12 months and all-cause death or myocardial infarction at 3 years

SECONDARY ENDPOINTS: Device performance, safety, efficacy, composite endpoints.

RESULTS: At 12 months, target-lesion revascularization, EES incidence = 2.5% vs. SES incidence = 5.0%. Log-rank P=0.34; HR 0.85: 95% CI (0.61 to 1.18). All-cause death, SES incidence = 2.5% vs. EES incidence = 1.9%. Log-rank P=0.23; HR 0.75: 95% CI (0.46 to 1.20).

CONCLUSION: EES was demonstrated to be non-inferior to SES with respect to target-lesion revascularization rate at 1 year. One-year clinical outcome after both EES- and SES-use was excellent with low rate of target-lesion revascularization and very low rate of stent thrombosis.