Results from the BIO-RESORT trial presented

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Results of a large-scale, multicenter study found that treatment with two thin-strut drug-eluting stents were both non-inferior to a durable polymer drug-eluting stent and showed favorable clinical outcomes at one year in treating an all-comers population with a high proportion of patients with acute coronary syndromes.

Findings from the BIO-RESORT (TWENTE III) trial were reported today at the 28th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. Sponsored by the Cardiovascular Research Foundation (CRF), TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine. The study was also published simultaneously in *The Lancet*.

"In patients with coronary artery disease treated with durable polymer-coated drug-eluting stents, the life-long presence of the polymer may delay arterial healing and even cause adverse clinical events," said Clemens von Birgelen, MD, PhD, Professor of Medicine at Thoraxcentrum Twente in Enschede, Netherlands. "Biodegradable polymer stents might improve long-term outcomes, but studies with early biodegradable polymer stents that had thick stainless steel struts (120 ?m) showed equivocal results. However, very thin-strut (60-81?m) biodegradable polymer stents that have flexible designs and thin, refined coatings are now available."

BIO-RESORT (TWENTE III) was a large-scale, investigator-initiated, assessor and patient-blinded, multicenter, three-arm trial that compared the safety and efficacy of two novel, very thin-strut biodegradable polymer stents to an established durable polymer stent (Resolute Integrity). Both biodegradable polymer stents have very thin struts but differ in the type, amount, distribution and degradation speed of their respective coating. The Synergy everolimus-eluting platinum chromium stent is the first and only biodegradable polymer drug-eluting stent approved by the FDA for clinical use in the United States and this was its first randomized assessment in an all-comers population. The Orsirio biodegradable polymer sirolimus-eluting cobalt chromium stent has been used clinically outside the United States.

Patients were randomly assigned (1:1:1) to treatment with the very thin-strut biodegradable polymer everolimus-eluting or sirolimus-eluting stents or the durable polymer zotarolimus-eluting stent at four sites in the Netherlands. The primary endpoint was a composite of safety (cardiac death or target-vessel-related myocardial infarction) and efficacy (target-vessel revascularization) at 12 months, analyzed by intention-to-treat (non-inferiority margin: 3.5%).

Of the 3,514 patients enrolled and analyzed, 2,449 (69.7%) had acute coronary syndromes, which included 1,073 (30.5%) ST-elevation myocardial infarctions. Twelve-month follow-up was available in 3,490 (99.3%) patients. The primary endpoint was met by 4.7% (55/1,172) of patients assigned to everolimus-eluting stents, 4.7% (55/1,169) assigned to sirolimus-eluting stents and 5.4% (63/1,173) assigned to zotarolimus-eluting stents. The non-inferiority of the everolimus-eluting stent and the sirolimus-eluting stent was confirmed (both: -0.7% absolute risk difference, 95% CI:-2.4-1.1; upper limit of 1-sided 95% CI: 0.8%, Pnon-inferiority