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Evaluation of the safety and efficacy of the Cobra PzF NanoCoated Coronary Stent (NCS) in 1,000 all-comer, consecutive, prospective, high-risk patient population: the e-Cobra registry

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds, Other Coronary Interventions

AIMS

The CeloNova COBRA PzF™ NanoCoated Coronary Stent is a *new stent design*, balloon expandable cobalt chromium alloy coronary stent with 71um thin struts that is pre-mounted on a custom rapid exchange balloon delivery catheter.

METHODS AND RESULTS

The alloy stent is surface treated with a nano-layer of Polyzene®-F (PzF) [Poly-bis(trifluoroethoxy) phosphazene]. Polyzene-F is an inorganic polymer with a high molecular weight. In vitro and in vivo studies have indicated that the nano-layer surface treatment is thrombo-resistant, and has anti-inflammatory and rapid endothelialization properties that help prevent tissue reactions. Pre-clinical studies have confirmed the thrombo-resistant and rapid healing properties and initial human studies have shown very promising clinical outcomes with low MACE, low TLR rates and no stent thrombosis at 1 year with 1 month DAPT.

1,000 all comers, consecutive patients, non-eligible for prolonged DAPT, are included from 18 sites. All patients undergoing treatment of "de novo" lesions in native coronary arteries, without limitation of number of stented vessels, saphanous vein graft and/or other bypass conduits were included. Primary objective is the assessment of MACE rate at 12 months (Cardiac death, MI, TLR) and secondary objective is the assessment of ST and TVR at 12 months, DAPT duration, patients in mono-therapy and bleeding per BARC definition. Patients' follow-up is performed at 1 month, 6 months and 12 months.

CONCLUSIONS

1,000 patients have been enrolled to date and 30 days results will be presented.