SMT announces positive results of S-Flex UK-II Registry at TCT 2023

Study synopsis

- The trial was presented on October 25, 2023 in the *PCI Outcomes III* session in San Francisco.
- 1835 patients were studied across 19 study centres in UK

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SMT (Sahajanand Medical Technologies), a pioneering healthcare company in India with a focus on innovative patient care in the cardiovascular sector, is pleased to announce promising data from its study, the Prospective S-FLEX UK-II Registry.

The S-FLEX UK-II Registry was designed to evaluate the safety and performance of the ultrathin Supraflex Cruz sirolimus-eluting stents (SES) in a diverse population of patients with coronary artery disease. This multicenter, single-arm study involved 19 sites across UK, with a total of 1835 patients enrolled between March 2020 and September 2021.

Study highlights:

- Study Design: Prospective, observational, multicenter, single-arm study
- Primary Objective: To evaluate the safety and performance of the ultrathin Supraflex Cruz SES in patients with coronary artery disease.
- Patient Population: All-comers patients requiring PCI (Stent implantation)
- Follow-up / Total Duration: 12 months (data presented at TCT 2023, San Francisco, October 23-26, 2023)
- Primary Endpoint: Target Lesion Failure (TLF), a composite of cardiac death, target vessel MI (TV-MI), and clinically driven target lesion revascularization (CD-TLR), at 12 months.

Prof. Azfar Zaman, Freeman Hospital, Newcastle Upon Tyne, United Kingdom Principal Investigator of the study stated, “The overall study results show consistently low clinical event rates with Supraflex Cruz in a real-world all-comers population from the United Kingdom. Importantly, the safety of Supraflex Cruz was once again confirmed in a high-risk subset of patients and lesion types.”

The study demonstrated, in the overall population, that TLF occurred in 0.7% of patients (0.3% cardiac death, 0.2% TV-MI, 0.2% CD-TLR) at 30 days and in 2.4% of patients (0.8% cardiac death, 0.8% TV-MI, 0.9% CD-TLR) at 12 months follow-up. The rate of definite stent thrombosis was 0.3% in the overall population at 12 months. The incidence of TLF and stent thrombosis in pre-specified subgroups were — 6.5% and 1% in patients with diabetes, 1.9% and none in bifurcation lesions, 2.6% and 0.3% in type B2/C lesions, and 2.8% and 0.3% in long lesions (>20 mm) respectively. at 12 months follow-up.

SMT's Chief Medical Officer Dr Krishna Sudhir commented, "This study adds to a convincing body of clinical evidence from several registries and two major randomized trials confirming the benefits of using Supraflex Cruz in patients with complex coronary artery disease."

This study offers compelling data to the interventional cardiology community, highlighting the safety and efficiency of Supraflex Cruz, and reaffirm SMT's unwavering commitment to advancing cardiovascular care.

About SMT

SMT is a global medical device company committed to make advanced medical technologies accessible to everyone around the world. With presence in 79 countries, SMT has achieved recognitions from the Ministry of Health Sciences & Technologies for its tremendous contributions in the field of coronary healthcare. SMT also pioneered the introduction of biodegradable polymers in the cardiovascular segment. SMT will continue the journey to heal hearts around the world by creating healthcare future promising for everyone.

About Supraflex Cruz

The Cruz design provides physicians access to difficult and tortuous lesions which are very challenging in their practice. The stent retains all the benefits of Supraflex stents or the previous "Supra" family of stents, viz, thin struts, a blend of proprietary biodegradable polymers to release the drug, high radial strength, and low crossing profile. Supraflex Cruz has a very large and extensive size matrix, covering diameters from 2.0 to 4.5 and lengths from 8 mm to 48 mm. This size matrix ensures no compromises in the coronaries for either physician or patient.

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