Positive Results Revealed in Clinical Trial COMPARE 60/80 for High Bleeding Risk Patients

Study Synopsis

- The findings will impact the interventional treatment of High Bleeding Risk patients.
- Data from 732 patients across 11 Dutch centres

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SMT (Sahajanand Medical Technologies), a leading medical device company in India, focused on innovative patient care in cardiovascular segment, today announced positive results of its recent clinical trial COMPARE 60/80 in a cardiology conference.

The study, conducted across 11 Dutch sites, was unveiled during the TCT 2023 at San Francisco, California. The Transcatheter Cardiovascular Therapeutics (TCT) conference is the Cardiovascular Research Foundation's (CRF) annual scientific symposium and the world's foremost educational forum specializing in interventional cardiovascular medicine.

Principal Investigator of the trial, Dr Pieter C. Smits from Maasstad Hospital, Rotterdam, Netherlands presented the primary endpoint data. The primary endpoint was net adverse clinical endpoints (NACE), defined as a composite of cardiovascular death, myocardial infarction, target vessel revascularization, stroke and bleeding events defined as BARC 3 or 5 at 12 months follow-up after the index PCI.

This was an investigator-initiated, multicenter, prospective randomized (1:1) trial, conducted from September 14, 2020, to August 01, 2022. A total of 732 patients were randomly assigned to either the Supraflex Cruz group (n=368) or the Ultimaster Tansei group (n=364).

Reflecting on the study, Dr Pieter C. Smits, shared, “In this randomized controlled trial in a high-risk group, the first head-to-head comparison in patients with the new ARC definition of high bleeding risk (HBR), Supraflex Cruz demonstrated outstanding clinical results, with non-inferiority to the Ultimaster Tansei stent. In the current changing landscape of PCI with progressively shorter dual antiplatelet therapy duration without increasing ischemic risk, the need for safe and effective DES becomes more important. In this context, Supraflex Cruz provides an excellent choice for physicians with its proven safety and potentially better outcomes for our patients.”

The study objective was to compare the outcome of the ultrathin stent strut Supraflex Cruz stent (60-micron stent struts) to the thin stent strut Ultimaster Tansei stent (80-micron stent struts) in an HBR PCI population. At the 12-month follow-up, the primary

endpoint of NACE was observed in 15.4% of patients within the Supraflex Cruz group and 17.1% of patients in the Ultimaster Tansei group, demonstrating the non-inferiority of the Supraflex Cruz stent compared to the Ultimaster Tansei stent (p=0.02). Importantly, a lower rate of target lesion revascularization was observed in the Supraflex Cruz group in comparison to the Ultimaster Tansei group (2.7% vs. 5.3%, p=0.078). Additionally, most other cardiac endpoints showed numerically lower values in the Supraflex Cruz group when compared to the Ultimaster Tansei group.

Chief Medical Officer at SMT, Dr Krishna Sudhir commented, "In yet another European randomized clinical trial, Supraflex Cruz has performed impressively, demonstrating low clinical event rates in a very high-risk subset of patients. This study confirms what the TALENT and FIRE randomized trials have previously shown, namely, an excellent efficacy and safety profile for the Supraflex Cruz stent in complex patients with coronary artery disease."

With one more positive outcome for Supraflex Cruz, SMT remains dedicated to pushing the boundaries of medical innovation, bringing hope and health to the patients worldwide.

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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* Ultimaster Tansei is a trademark stent from Terumo Interventional Systems

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