



## Press Release

### **Supraflex Cruz RCT in High bleeding Risk patients now published in *Circulation***

#### **For Immediate Release**

**Mumbai, India, 16 October 2024**

SMT (Sahajanand Medical Technologies) is proud to announce the publication of the COMPARE 60/80 HBR trial results in *Circulation: Cardiovascular Interventions\**, a leading cardiovascular journal. Led by Dr. Pieter C. Smits and a distinguished team of international researchers, the trial compares the performance of SMT's biodegradable-polymer sirolimus-eluting Supraflex™ Cruz™ stent with the biodegradable-polymer \*Ultimaster™ Tansei™ stent in patients with high bleeding risk (HBR) undergoing abbreviated dual antiplatelet therapy (DAPT).

The COMPARE 60/80 HBR trial is the first randomized clinical trial conducted after the release of the ARC HBR (Academic Research Consortium for High Bleeding Risk) guidelines, enrolling only HBR patients as defined by these criteria. The study was carried out across 11 centers in the Netherlands, enrolling 741 patients at high risk of both bleeding and ischemia, making it one of the most comprehensive trials in this high-risk population.

The trial results demonstrate the noninferiority of the Supraflex Cruz stent compared to the Ultimaster Tansei stent in terms of net adverse clinical events (NACE) at 12 months, with event rates of 15.4% and 17.1%, respectively (P=0.02 for noninferiority). Notably, the Supraflex Cruz stent showed a significant reduction in clinically driven target lesion revascularization (TLR) rates and very low rates of stent thrombosis, despite the fact that the enrolled patients were at substantial risk for bleeding and ischemic events.

#### **Key Highlights from the Study:**

- **Clinically driven TLR rates** were significantly lower with Supraflex Cruz, supporting its superior performance in reducing the need for repeat interventions.
- **Stent thrombosis rates** with Supraflex Cruz were impressively low, even in this high-risk population, underscoring the safety of the design.
- This trial marks the **first major study** to include **only HBR patients** in accordance with the ARC HBR guidelines, making it a pioneering study for managing patients who are at both high bleeding and ischemic risk.

Chief Medical Officer at SMT, Dr Krishna Sudhir commented, "In one more European randomized clinical trial, Supraflex Cruz has demonstrated outstanding performance, with low clinical event rates in a very high-risk subset of patients. This study extends findings from the TALENT and FIRE randomized trials, confirming an excellent efficacy



and safety profile for the Supraflex Cruz stent in patients with coronary artery disease at high risk of bleeding.”

Principal Investigator, Dr. Pieter C. Smits of Maasstad Hospital, Rotterdam shared his views, saying, “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 excellent clinical outcomes, with non-inferiority to the Ultimaster Tansei stent. As dual antiplatelet therapy (DAPT) durations have progressively decreased after PCI, the need for safe and effective DES has become even more important. In this context, Supraflex Cruz provides an excellent choice for physicians with its proven safety and potentially better outcomes for our patients, even in the setting of short DAPT.”

\*Ultimaster™ Tansei™ is a trademark stent of Terumo Interventional Systems.

\*Circulation: Cardiovascular Interventions is trademark journal of The American Heart Association

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### **About SMT (Sahajanand Medical Technologies)**

SMT is a global leader in cardiovascular medical devices, specializing in drug-eluting stents and structural heart disease solutions. Operating in over 80 countries, SMT is dedicated to advancing patient care through innovative medical technologies and clinical excellence, as demonstrated by the Multivessel TALENT trial. 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.

### **About Supraflex Cruz**

The Cruz design provides physicians access to difficult and tortuous lesions which are particularly challenging in their practice. The stent retains all the benefits of Supraflex stents or the previous “Supra” family of stents, viz, a blend of proprietary biodegradable polymers to release the drug, high radial strength, and low crossing profile. Supraflex Cruz has a 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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