SMT Completes Enrolment of Cruz HBR Registry to further evaluate the Safety and Efficacy of Supraflex Cruz in High Bleeding Risk patients

Release summary points

- **1200 {800 non-High Bleeding Risk (non-HBR) and 400 High Bleeding Risk (HBR) patients are involved in the registry}**
- **26 sites in 3 countries (France, Germany, Switzerland)**

Mumbai/ November 4, 2020

SMT (Sahajanand Medical Technologies Pvt. Ltd.), global manufacturer of cardiovascular medical devices, today announced that it has completed the patient enrolment for **Cruz HBR Registry**. Patient enrolment had started on **February 19, 2020 and ended on October 16, 2020.** The registry was conducted in France, Germany and Switzerland comprising of 26 sites.

This registry is a prospective, multi-center, single-arm registry to evaluate the safety and efficacy of Supraflex Cruz sirolimus-eluting coronary stent system in the treatment of all-comer patients with coronary artery disease by Percutaneous Coronary Intervention, to confirm the results from the *TALENT* trial in real life.

The secondary objective of this registry is to demonstrate that Supraflex Cruz stent is non inferior to BioFreedom™ stent amongst High Bleeding Risk patients. High bleeding risk patients are very complex set of population who are at a high risk of bleeding and high ischemic risk. The benefits of ultrathin Supraflex Cruz stent in this patient population will be evaluated for the first time in this study. The CRO for this study is Cardiovascular European Research Centre (CERC), France which carries a high reputation of conducting many landmark studies very successfully.

The study evaluates a total of 1200 patients amongst which 800 patients are having non-High Bleeding Risk and 400 patients possess bleeding risk factor. The study has been commenced under Principal Investigator and Senior Interventional Cardiologist Prof. Christoph Naber (Klinikum Wilhelmshaven), Germany.

Speaking more about the evaluation process, Principle Investigator Prof. Christoph Naber said," I am sure the results of this registry will prove very useful for the colleagues out there in the Cath labs. While TALENT trial showed excellent data for the Supraflex family of Stent, Cruz HBR will extend our knowledge to all-comers and patients with high bleeding risk."

Adding on the study front, the CEO of CERC, Dr Marie -Claude Morice said," CERC team is very grateful to the Cruz HBR investigators, who recruited faster than expected all 1200 patients despite the Covid-19 period. Entire CERC team was mobilized to follow this rapid pace effectively. »

Study pointers
Total No. of Patients: 1200 (800 non-High Bleeding Risk (non-HBR) and 400 HBR)
Principal Investigator: Prof. Christoph Naber, Klinikum Wilhelmshaven, Germany
CRO: Cardiovascular European Research Center (CERC), France
Locations: 26 sites in 3 countries (France, Germany, Switzerland)
Study Start Date: February 19, 2020

The results of HBR Cruz Registry are expected by the end of year 2021.

BioFreedom™ is a polymer- and carrier-free Drug Coated Stent with BA9™ (DCS) by Biosensors International.
*Supraflex Cruz is a trademark of Sahajanand Medical Technologies Pvt. Ltd. or its affiliates.

About SMT
SMT is a global medical device company committed to making advance medical technologies accessible to everyone around the world. With a presence in over 75 countries, SMT has achieved recognition from the Government of India for its tremendous contributions in the field of Cardiovascular healthcare. SMT has also led the development of innovative biodegradable polymer coating technology in coronary stent system. SMT will continue the journey to healing hearts around the world by creating a healthcare future promising for everyone.

About Supraflex Cruz
Cruz design provides physicians an access to difficult and tortuous lesions which were very challenging in their practice. The stent retains all the benefits of the Supraflex stent or the previous "Supra" Family of stents, viz, Ultrathin strut thickness (60 microns for all diameters and lengths), blend of proprietary biodegradable polymers to release the drug, very thin layer of polymers, high radial strength, low crossing profile. The Supraflex Cruz has a very large and extensive size matrix. 1 set consist of 88 skus and covers diameters from 2.0 to 4.5 and lengths from 8 mm to 48 mm. This size matrix ensures that the physician and the patient does not need to make any compromise of accommodating a shorter or a longer stent inside the coronaries.

About CERC
The CERC is a unique Contract Research Organization based in Massy, France, and presided by four medical directors, Dr. Marie-Claude Morice, Dr. Philip Urban, Dr. Davide Capodanno and Dr. Philippe Garot. The CERC was created with the aim of establishing a reputable high-quality dedicated CRO in Europe. Its objectives are to underpin European clinical trials and academic leadership, act as a global CRO and support young scientific leaders. The prestigious members of the CERC's Medical

Advisory Council provide unparalleled guidance and expert support in a broad range of clinical trials dedicated to the assessment of interventional coronary and peripheral revascularization, structural and valvular heart disease treatments and adjunctive pharmacology. The CERC has an excellent track record in regulatory guidance, trial design, global study management and monitoring, CEC/DSMB coordination, core-lab activities for pre- and post- market drug and device trials. The CERC's industrial partners attach great importance to finding cost-effective models which do not compromise quality. The CERC has established a network of structures (CERC Asia, CERC Deutschland) in order to achieve this objective.

Media Contact:
Tejaswini Kamalkar
Manager | Corporate Communications
Mail ID: tejaswini.kamalkar@smt.in
Contact no: +91 8291 371332 / 9930456453