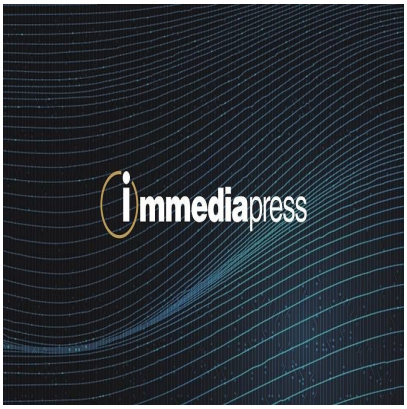

SPARX Global Randomized Controlled Trial by Translumina Initiated to Advance Evidence for Drug-Coated Balloons in Complex Coronary Disease

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LUCERNE, Switzerland and NEW DELHI, Oct. 12, 2026 /PRNewswire/ â?? The SPARX Global Randomized Controlled Trial (RCT) has been officially initiated, marking the launch of the multinational randomized trial evaluating a drug-coated balloon (DCB)-first strategy against contemporary drug-eluting stents (DES) in patients with complex coronary artery disease.Designed to generate comparative evidence, SPARX aims to address key unanswered clinical questions regarding the safety, efficacy, and long-term outcomes of a â??leave nothing behindâ?• treatment strategy, with the potential to shape future clinical practice and international guideline recommendations.

As one of the contemporary multinational randomized DCB trials undertaken to date, SPARX is expected to generate the evidence needed to define the future role of drug-coated balloons in complex coronary intervention.

Addressing an Unmet Clinical Need

Prof. Adnan Kastrati, Study Chairperson, German Heart Centre, Germany, highlighted the clinical rationale of the trial:

â??Despite advances in drug-eluting stent technology, permanent metallic implants may be associated with late adverse events beyond the first year. Drug-coated balloons, which leave no permanent implant, offer a therapeutic alternative, supported by growing evidence across multiple lesion subsets. However, randomized evidence in complex coronary artery disease remains limited. SPARX has been designed with the aim to further define the role of drug-coated balloons in contemporary coronary intervention.â?•

Prof. Florim Cuculi, Global Lead Principal Investigator, Luzerner Kantonsspital, Switzerland commented on the trialâ??s significance:

â??SPARX has been designed as a multinational randomized trial comparing a DCB-first strategy with contemporary drug-eluting stents across a broad spectrum of complex coronary lesions. The study will enroll 1,380 patients across 10 countries with two-year follow-up and a one-year Device-Oriented Composite Endpoint (DOCE) as the primary endpoint. In addition, SPARX will provide randomized head-to-head comparative data between two established paclitaxel-coated balloon technologies. We believe SPARX aims to define the role of drug-coated balloons in contemporary coronary intervention.â?•

Dr. Praveen Chandra, Global Co-Principal Investigator, Medanta- The Medicity, Gurgaon, India mentioned:

â??India represents one of the worldâ??s highest-risk coronary artery disease populations, with a high prevalence of diabetes and diffuse complex coronary disease. This makes it an important setting for evaluating drug-coated balloons in contemporary clinical practice. We believe SPARX intends to generate clinically relevant evidence that support treatment decisions for physicians in contemporary coronary intervention.â?•

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Mr. Sudipta Ghosh, Chief executive officer- cardiovascular, Translumina Therapeutics Private Limited, stated:

â??SPARX represents a significant milestone in our commitment to advancing evidence-based innovation in interventional cardiology. The trial is evaluating the ProtÃ©gÃ©â?¢ Paclitaxel-Coated Balloon, which pairs a distinctive drug application method with our proprietary technology to help preserve drug integrity during delivery. Through SPARX, we aim to generate high-quality randomized clinical evidence that will help define the role of drug-coated balloons and the â??leave nothing behindâ?? strategy in complex coronary artery disease, ultimately supporting physicians in delivering the best possible care for their patients.â?•

The SPARX Global RCT is sponsored by Translumina Therapeutics Private Limited, India.

CTRI Number- CTRI/2026/04/109375

ClinicalTrials.gov ID â?? NCT07397845

About Translumina

Translumina Therapeutics Private Limited, a material subsidiary of Integris Medtech Limited (formerly known as Integris Health Private Limited)., is a global cardiovascular medical technology company focused on advancing interventional cardiology through innovative technologies and evidence-based clinical research. Its portfolio includes drug-eluting stents, drug-coated balloons and balloon catheters. Supporting physicians in more than 65 countries, the company operates manufacturing facilities in India, Germany and the Netherlands under internationally recognized quality systems, including EU MDR CE, EU MDD CE and EN ISO 13485.

For more information, visit integrismedtech.com.

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Integris MedTech Limited (formerly known as Integris Health Private Limited) is proposing, subject to receipt of requisite approvals, market conditions and other considerations, to make an initial public offer of its equity shares (â??Equity Sharesâ?•) and has filed a draft red herring prospectus dated October 9, 2025 (â??DRHPâ?•) with the Securities and Exchange Board of India (â??SEBIâ?•) and the stock exchange(s) where the Equity Shares are proposed to be listed (the â??Stock Exchangesâ?•). The DRHP is available on the websites of Integris Medtech Limited at https://integrismedtech.com/investors/, SEBI at www.sebi.gov.in, the websites of the book running lead managers, ICICI Securities Limited, Axis Capital Limited, Citigroup Global Markets India Private Limited and IIFL Capital Services Limited (formerly known as IIFL Securities Limited) at www.icicisecurities.com, www.axiscapital.co.in, www.online.citibank.co.in/rhtm/citigroupglobalscreen1.htm and www.iiflcapital.com, respectively, the website of the National Stock Exchange of India Limited at www.nseindia.com and the website of the BSE Limited at www.bseindia.com.

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