Solaris Endovascular Reports Positive 12-Month Results from the Solaris SX™ Iliac Multicenter Study

European real-world data show strong Solaris SX™ performance in PAD, complementing findings from the DEScover sirolimus-eluting program

Solaris SX Flexibility

NEW YORK, NY, UNITED STATES, November 21, 2025 / EINPresswire.com/ -- Solaris Endovascular today announced encouraging 12-month results from the Solaris SX Iliac Post-Market Clinical Follow-Up (PMCF) Study following the presentation of data at VEITHsymposium 2025 in New York City. The prospective, physician-initiated multicenter trial demonstrated high primary patency, low reintervention rates, and a favorable safety profile across nine European sites.

• Greater than 95% primary patency at six months and 94% at 12 months.

• Ankle-Brachial Index improvement from 0.547 at baseline to 0.927 at 12 months

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> *Giacomo Isernia, MD*

"The twelve-month results from this multicenter study show consistent and durable performance of the Solaris SX covered stent across challenging iliac anatomy," said Giacomo Isernia, MD, PhD, Azienda Ospedaliera di Perugia, Italy, the study's Principal Investigator. "We observed high patency, very few reinterventions, and strong safety outcomes across nine European sites. The performance of Solaris SX in this study reflects the integrity of the stent design and indicates potential utility in broader peripheral arterial applications."

These Solaris SX results build on the momentum from the Solaris DE™ DEScover Trial, which

reported strong six-month interim outcomes in October 2025. The DEScover study, the first-in-human evaluation of a sirolimus-eluting self-expanding covered stent, demonstrated 95% TLPP (Target Lesion Primary Patency) at six months, 100% procedural success, and no device-related serious adverse events through 30 days. The sirolimus-eluting DE version and the Solaris SX mechanical scaffold together form a unified platform strategy aimed at addressing unmet needs across dialysis access and peripheral artery disease.

“These findings further validate Solaris SX as a robust mechanical scaffold and a critical foundation for the Solaris drug-eluting covered stent,” said Marco Costa, MD, PhD, CEO of Scitech Medical and Chief Medical and Scientific Officer of Solaris Inc. “Together, this outstanding performance in the iliac arteries results and the encouraging DEScover drug-eluting data underscore a versatile platform to address the unmet needs of millions of patients suffering from peripheral artery disease and dialysis access failures .”

About the DEScover Trial
The DEScover Trial is a prospective, multicenter feasibility study evaluating the Solaris DE sirolimus-eluting electrospun PTFE covered stent in 120 patients with failing AVF and AVG access. Interim six-month data showed strong safety and efficacy versus historical PTA and non–drug-eluting covered stent benchmarks.

Solaris DE builds on the Solaris SX metallic-edge platform and combines:
• Mechanical scaffold: self-expanding nitinol for durability
• Structural barrier: electrospun PTFE to limit neointimal migration
• Biological barrier: controlled sirolimus release at the stent edges

This tri-layer design delivers sirolimus directly to the vessel wall and supports patency beyond the stent edge. Solaris SX (non-drug version) is approved in 45 countries for dialysis access, iliac and peripheral arterial disease, with an FDA IDE submission planned for December 2025.

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