Solaris Endovascular Exceeds Enrollment Milestone for DEScover Trial; Interim Data to be Shared at Vascular Conferences

80% of Patients Now Enrolled in Pioneering Drug-Eluting Covered Stent Graft Study

Solaris DE Logo

NEW ORLEANS, LA, UNITED STATES, September 2, 2025 /EINPresswire.com/ -- Solaris Endovascular, Inc., a growth-stage U.S.-based medical device company specializing in advanced endovascular solutions, today announced that 80% of patients have now been enrolled in the pivotal DEScover randomized clinical trial. This groundbreaking study — the first to evaluate sirolimus-eluting covered stent grafts — is ahead of schedule, with 96 of the planned 120 patients enrolled.

> We are very pleased with the pace of enrollment in the DEScover trial and look forward to sharing interim data at upcoming conferences this fall"
>
> *Randy Hubbell*

As a next step, 6-month interim data will be presented by Dr. Leonardo Harduin, Principal Investigator, at three upcoming international meetings:

- TCT (Transcatheter Cardiovascular Therapeutics) – October 26, San Francisco
- CiDA (Controversies in Dialysis Access) – November 1, Boston
- VEITH Symposium – November 21, New York City

The DEScover trial is randomizing 120 patients with native arteriovenous fistulae (AVF) and prosthetic arteriovenous graft (AVG) to balloon angioplasty vs. the sirolimus-releasing electrospun ePTFE covered Solaris DE stent. The primary endpoint is Target Lesion Primary Patency at 6 months. This analysis will represent the first-ever presentation of data evaluating drug elution from the metal edges of a covered endovascular stent designed to prevent edge restenosis, one of the last unsolved challenges in vascular intervention.

Addressing Large Market Opportunity

Dialysis access dysfunction and peripheral artery disease remain high-cost burdens, with U.S. end-stage kidney disease costs exceeding $59 billion in 2020. Covered stents have proven critical in prolonging hemodialysis access function and reducing the frequency of painful, costly

reinterventions compared with balloon angioplasty.

The Solaris DE covered stent has been designed to address these challenges by combining three critical elements: a mechanical scaffold that reinforces and supports the vessel wall; a structural barrier of next-generation impermeable electrospun PTFE that protects the vessel wall and blocks cell migration; and a biological barrier of controlled, prolonged sirolimus release through a biodegradable polymer that inhibits smooth muscle proliferation and provides a key distinction from balloon-coated technologies. Together, these features address a critical unmet clinical need and represent the first comprehensive solution to restenosis in dialysis access and peripheral vascular disease.

Dr. Leonardo Harduin, Principal Investigator, added: “Solaris DE is more than an incremental advance; it’s the first real solution to edge restenosis, with the potential to transform dialysis access and vascular care worldwide.”

Upcoming Corporate Milestone
Solaris also announced that CEO Randy Hubbell will present a corporate update at LSI Europe ‘25 in London on September 8, 2025, highlighting Solaris’ 2025 clinical and business achievements.

About Solaris Endovascular, Inc.
Solaris Endovascular is a growth-stage U.S.-based medical device company advancing the first and only drug-eluting covered stent graft platform worldwide. With a proven commercial product (Solaris SX) and its transformational next-generation program (Solaris DE), Solaris is dedicated to improving long-term outcomes for patients with dialysis access dysfunction and peripheral artery disease. Solaris holds worldwide rights to the Solaris technology platform, supported by multiple clinical studies, MDR certification, and ongoing global commercialization.
For more information, please visit: www.solarisendovascular.com

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