



## Silk Road Medical Announces Post Approval Study for the Treatment of Standard Surgical Risk Patients using TCAR

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SUNNYVALE, Calif., June 15, 2022 (GLOBE NEWSWIRE) -- Silk Road Medical, Inc. (Nasdaq: SILK), a company focused on reducing the risk of stroke and its devastating impact, today announced a prospective study to evaluate the TCAR® system in the treatment of standard surgical risk patients with carotid artery disease. The post-market study, called ROADSTER 3, will fulfill the U.S. Food and Drug Administration's (FDA) condition of approval for the recent expansion of labeling for the ENROUTE® Transcarotid Stent System, which now includes patients at high and standard risk of complications from carotid endarterectomy (CEA).

"ROADSTER 3 presents a significant opportunity to further build on the substantial clinical evidence supporting TCAR," said Erica Rogers, President and Chief Executive Officer of Silk Road Medical. "Strong clinical evidence has always been the backbone of our strategy to drive adoption, and to ensure every eligible patient has access to a less invasive treatment option."

ROADSTER 3 is a prospective, multi-center, single-arm study designed to assess the real-world treatment of standard surgical risk patients with carotid artery disease using TCAR. The study targets a maximum enrollment of 400 patients across approximately 50 sites, and the primary endpoints include a composite of major adverse events (death, stroke, or myocardial infarction) through 30 days post-procedure, plus ipsilateral stroke from day 31 to 365 post-procedure. The incidence of cranial nerve injury within 30 days post-procedure is a key secondary endpoint. The study is led by Co-National Principal Investigators: Dr. Marc L. Schermerhorn, Chief, Division of Vascular and Endovascular Surgery at Beth Israel Deaconess Medical Center, Dr. Meghan Dermody, Chief, Division of Vascular Surgery at Lancaster General Hospital, and Dr. Jeffrey Jim, Chief of Vascular and Endovascular Surgery, Allina Health Minneapolis Heart Institute.

"This study is providing physicians with the unique opportunity to participate in a first-ever prospective study to demonstrate the safety and efficacy of TCAR among the standard surgical risk patient population," said Dr. Jeffrey Jim. "I'm honored to be included as Principal Investigator and eagerly await clinical results that will help expand a less invasive treatment option for carotid patients regardless of their surgical risk."

For more information on the ROADSTER 3 study protocol, visit: <https://clinicaltrials.gov/ct2/show/NCT05365490>

### About Silk Road Medical's TCAR Procedure with the ENROUTE Transcarotid Neuroprotection and Stent Systems

TransCarotid Artery Revascularization is a clinically proven procedure combining surgical principles of neuroprotection with minimally invasive endovascular techniques to treat blockages in the carotid artery at risk of causing a stroke. The ENROUTE Transcarotid Stent is intended to be used in patients at high risk and standard risk for complications from CEA, in conjunction with the ENROUTE Transcarotid Neuroprotection System (NPS) during the procedure. The ENROUTE Transcarotid NPS is a first in class device used to directly access the common carotid artery and initiate high rate temporary blood flow reversal to protect the brain from stroke while delivering and implanting the ENROUTE Transcarotid Stent.

### About Silk Road Medical

Silk Road Medical, Inc. (NASDAQ: SILK), is a medical device company located in Sunnyvale, California and Plymouth, Minnesota, that is focused on reducing the risk of stroke and its devastating impact. The company has pioneered a new approach for the treatment of carotid artery disease called TransCarotid Artery Revascularization (TCAR). TCAR is a clinically proven procedure combining surgical principles of neuroprotection with minimally invasive endovascular techniques to treat blockages in the carotid artery at risk of causing a stroke. For more information on how Silk Road Medical is delivering brighter patient outcomes through brighter clinical thinking, visit [www.silkroadmed.com](http://www.silkroadmed.com) and connect on [Twitter](#), [LinkedIn](#) and [Facebook](#).

### Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These statements include statements related to expectations regarding patient treatment. Such statements are based on current assumptions that involve risks and uncertainties that could cause actual outcomes and results to differ materially. These forward-looking statements speak only as of the date hereof and should not be unduly relied upon. Silk Road Medical disclaims any obligation to update these forward-looking statements.

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