



Silk Road Medical Announces First Patient Enrolled in ROADSTER 3 Post Approval Study Evaluating TCAR® System in the Treatment of Standard Surgical Risk Patients

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SUNNYVALE, Calif., Sept. 07, 2022 (GLOBE NEWSWIRE) -- Silk Road Medical, Inc. (Nasdaq: SILK), a company focused on reducing the risk of stroke and its devastating impact, today announced enrollment of the first patient in ROADSTER 3, the first prospective, multi-center, single-arm study to assess real-world treatment of standard surgical risk (SSR) patients with carotid artery disease using TCAR. The procedure was performed by Dr. Animesh Rathore at Sentara Norfolk General Hospital in Norfolk, VA.

ROADSTER 3 is a post-approval study designed to prospectively evaluate real world use of TCAR among SSR patients and will enroll a maximum of 400 per protocol patients across up to 60 sites. The primary endpoints include a hierarchical 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. With the enrollment of the first patient, the launch of the ROADSTER 3 study achieves the first of a series of milestones set forth by the FDA's post-approval requirements.

"The successful enrollment of the first patient in ROADSTER 3 by Dr. Rathore and the team at Sentara Norfolk General Hospital represents a significant milestone in our efforts to extend the body of clinical evidence supporting TCAR in this expanded patient population," said Erica Rogers, President and Chief Executive Officer of Silk Road Medical. "Our goal with the study is to confirm the safety and efficacy of TCAR in a prospective real-world standard surgical risk patient population to firmly establish this less invasive treatment option for all carotid stenosis patients."

"Positive outcomes in high surgical risk patients treated with TCAR have been well documented over the years," said Dr. Rasesh M. Shah, site Principal Investigator at Sentara Norfolk General Hospital for the ROADSTER 3 study. "A study to confirm the efficacy of TCAR in the treatment of standard surgical risk patients is incredibly valuable as the physician community looks to improve its overall approach to treating carotid patients, independent of their surgical risk. I'm honored to be participating in this first ever study to collect prospective data on the treatment of a recently approved patient population using TCAR."

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

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

TransCarotid Artery Revascularization is our 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 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 enrollment and treatment and the results of clinical studies. 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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