

ROADSTER-2 Demonstrates Compelling Patient Outcomes with Strong Safety Profile

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Final Results Presented in Late-Breaking Session at Society for Vascular Surgery 2019 Vascular Annual Meeting

NATIONAL HARBOR, Md., June 15, 2019 (GLOBE NEWSWIRE) -- <u>Silk Road Medical, Inc.</u> (Nasdaq: SILK), a company focused on reducing the risk of stroke and its devastating impact, today announced positive final results for the company's ROADSTER-2 post-marketing study evaluating real world use of the ENROUTE® Neuroprotection and Stent Systems in TransCarotid Artery Revascularization (TCAR) procedures.

In the late-breaking session at the Society for Vascular Surgery 2019 Vascular Annual Meeting (VAM), Dr. Vikram Kashyap, Chief of Vascular Surgery and Endovascular Therapy at University Hospitals Case Medical Center (Cleveland, OH) and National Co-Principal Investigator of ROADSTER-2, reported that the study demonstrated compelling patient outcomes with low stroke and combined stroke and death rates of 0.6% and 0.8%, respectively, in 632 high surgical risk patients enrolled across 42 sites. Seventy percent (70%) of patients enrolled in the study were from physicians new to TCAR.

"The results of ROADSTER-2 continue to demonstrate the safety, effectiveness and clinical advantages of TCAR, especially given that a majority of the TCAR procedures were performed by a broad group of physicians with no previous TCAR experience," Dr. Kashyap said. "The study results highlight the short learning curve of the TCAR procedure and its remarkable consistency and reproducibility, and, I believe, will further encourage physicians to broadly adopt the TCAR procedure."

Designed as a follow-on study to the pivotal ROADSTER trial, ROADSTER-2 is a prospective, multi-center study designed to assess the real-world usage of the ENROUTE Transcarotid Stent when used with the ENROUTE Transcarotid Neuroprotection System by physicians of varying experience with the TCAR procedure. The study met its primary endpoint of procedural success, defined as acute device and technical success in the absence of stroke, death or myocardial infarction (MI) at 30 days, at 97.9%.

Significant findings from the study showed TCAR to have low rates of 30-day major adverse events, including:

- 1.7% stroke, death and MI
- 0.8% stroke and death
- 0.6% stroke, including 0.6% in symptomatic patients, 0.5% in females, and 1.1% in patients age greater than 75

In addition, ROADSTER-2 showed lower rates of acute (1.3%) and permanent (0.5%) cranial nerve injury than is typically observed for patients receiving carotid endarterectomy (CEA), the current standard of care.

"The mounting clinical evidence base demonstrates the compelling patient benefits of TCAR, which we believe will further support physician confidence and adoption. The data from ROADSTER-2, taken together with recent updated results from the TCAR Surveillance Project, supports the case for TCAR as the standard of care in high surgical risk patients," said Erica Rogers, Silk Road Medical's Chief Executive Officer.

About TCAR with the ENROUTE Transcarotid Neuroprotection and Stent System

TCAR (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 conjunction with the ENROUTE Transcarotid Neuroprotection System (NPS) during the TCAR 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. is a medical device company located in Sunnyvale, California, 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.

ENROUTE is a registered trademark of Silk Road Medical, Inc.

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