Silk Road Medical Announces FDA Approval of Expanded Indications for the ENROUTE® Transcarotid Stent System

May 2, 2022

SUNNYVALE, Calif. – May 2, 2022 (GLOBE NEWSWIRE) – Silk Road Medical, Inc. (Nasdaq: SILK), a company focused on reducing the risk of stroke and its devastating impact, today announced that that the U.S. Food and Drug Administration (FDA) approved expanded indications for the ENROUTE stent to include patients at standard risk for adverse events from carotid endarterectomy (CEA). Previously, the stent was approved for use only in patients with anatomic or physiological criteria that put them at high risk of complications from more invasive surgical procedures.

"This is the first time in history that a stent-based approach has demonstrated non-inferiority in stroke and death rates relative to CEA, with our TCAR® system offering the added benefit of significantly reduced cranial nerve injury risk," said Erica Rogers, President and Chief Executive Officer of Silk Road Medical. "This label expansion levels a playing field once dominated by open surgical techniques, allowing an expanded number of patients and physicians access to the benefits of a less invasive treatment option."

Silk Road Medical had previously submitted a PMA supplement, which included data extracted from the Vascular Quality Initiative. The surveillance data included in the submission represented real-world outcomes in 20,264 patients considered at standard surgical risk. Those data demonstrated that use of Silk Road Medical's TCAR® system is statistically non-inferior in stroke and death outcomes to CEA, while showing a ninefold reduction in cranial nerve injury (CNI) (2.7% vs 0.3%, p=<0.001).

"Pairing the right patient with the right treatment results in significantly improved physician and patient experiences and outcomes. This label expansion for TCAR is a welcomed and vital advancement in the treatment paradigm for patients at risk of stroke," said Dr. Marc L. Schermerhorn, Coordinating Investigator of the analysis used to support the approval and Chief, Division of Vascular and Endovascular Surgery at Beth Israel Deaconess Medical Center. "The decision regarding which patients to treat with TCAR is no longer restricted to patients at high surgical risk, providing a greater opportunity for the care-team to pursue the less invasive approach for a broader set of their patients."*

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, 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 that it has 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 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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**The quote from Dr. Marc Schermerhorn has been revised since the issuance of the original press release on May 2, 2022.*