

Silk Road Medical Announces Expanded Medicare Coverage for TCAR in Standard Surgical Risk Patients

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SUNNYVALE, Calif., June 02, 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 the Centers for Medicare and Medicaid Services (CMS), through collaboration with the Society of Vascular Surgery's Patient Safety Organization (SVS PSO) and their Vascular Quality Initiative (VQI), has expanded coverage for TCAR to include standard surgical risk patients within the VQI's TCAR Surveillance Project (TSP). This decision is effective immediately and comes on the heels of the recent Food and Drug Administration (FDA) approval for expanded indications for the ENROUTE® Transcarotid Stent System to include patients at high risk and standard risk for adverse events from carotid endarterectomy (CEA).

"This CMS coverage expansion ensures that many more carotid artery disease patients who require treatment have the opportunity to benefit from the minimally invasive approach that our TCAR® system offers," said Erica Rogers, President and Chief Executive Officer of Silk Road Medical. "We're grateful to the teams at the FDA, CMS, and SVS for their valuable collaboration and partnership in recognizing the weight of real-world evidence supporting TCAR use in this expanded patient population and the necessity of working to prevent the debilitating impacts of stroke on individuals, their families, and the health system as a whole."

The TCAR Surveillance Project is a prospective, national, open ended observational registry designed to monitor the safety and effectiveness of transcarotid stents placed directly into the carotid artery while reversing blood flow within the carotid artery to reduce stroke risk. Hospitals and physicians participating in the TCAR Surveillance Project can obtain reimbursement for TCAR procedures by submitting claims under the <u>National</u> <u>Clinical Trial number NCT02850588</u>. Reimbursement for TCAR within the TSP will now apply to Medicare beneficiaries who are deemed to be at high risk and standard risk for adverse events from CEA.

"With substantial real-world evidence of over 45,000 procedures performed to date with compelling clinical and patient benefits, TCAR has become the less invasive standard in stroke prevention treatment options," said Dr. Sumaira Macdonald, Executive Medical Director of Silk Road Medical. "The expanded coverage and access are encouraging for patients looking for a reliable, minimally invasive treatment option for carotid disease regardless of their surgical risk classification."

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

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 adverse events from CEA, in conjunction with the ENROUTE Transcarotid Neuroprotection System (NPS). 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 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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