InspireMD Announces First U.S. Commercial TCAR Procedures Using the FDA-Approved CGuard® Prime TransCarotid Stent System

November 18, 2026

- First commercial cases mark return of the CGuard Prime platform to the U.S. market -

- Milestone expands commercial application of proprietary MicroNet™ Mesh-covered CGuard Prime stent platform to include transcarotid artery revascularization ("TCAR") procedures –

MIAMI, Nov. 18, 2026 (GLOBE NEWSWIRE) -- InspireMD, Inc. (Nasdaq: NSPR) ("InspireMD" or the "Company"), developer of the CGuard® Prime Carotid Stent for the prevention of stroke, today announced the successful completion of the first U.S. commercial transcarotid artery revascularization ("TCAR") procedures utilizing its CGuard ® Prime TransCarotid Stent System, following U.S. Food and Drug Administration ("FDA") pre-market approval ("PMA") of the device on November 9, 2026. Among the first physicians to perform commercial cases with the system were **Brett Almond, M.D., at Bay Surgical Specialists, greater Tampa Bay area, Florida**; **Gregory T. Clabeaux, D.O., at Sisters of Charity Hospital, part of Catholic Health, in Buffalo, New York**; and **Bradley R. Grimsley, M.D., at Baylor Scott & White in Dallas, Texas**.

The first commercial cases mark an important step in the U.S. rollout of the CGuard® Prime TransCarotid Stent System, a delivery system designed for transcarotid access. The system enables physicians to use InspireMD's proprietary MicroNet™ mesh-covered stent technology during TCAR procedures with a compatible FDA-cleared neuroprotection system.

"Completing our first commercial TCAR cases so soon after the FDA approval represents a meaningful transition from regulatory achievement to clinical adoption," said Marvin Slosman, Chief Executive Officer of InspireMD. "It demonstrates our ability to bring CGuard Prime's differentiated implant technology to physicians using the transcarotid approach and marks the beginning of a new phase of our U.S. commercialization strategy."

Dr. Almond is a high-volume vascular surgeon in the greater Tampa Bay area with more than 15 years of experience treating carotid artery disease. He performs over 60 carotid interventions annually and commented, "CGuard Prime is that next-generation technology in carotid stenting. The MicroNet mesh-covered stent offers decreased embolization, restenosis and complications for patients with the potential to improve long-term outcomes."

Dr. Clabeaux is an attending vascular surgeon in Buffalo, New York, who has practiced at Sisters of Charity Hospital, part of Catholic Health, for 11 years. He performs over 50 carotid procedures annually. "The CGuard Prime stent is a significant innovation and is exactly what clinicians have needed for complex plaque at the carotid bifurcation during TCAR procedures," said Dr. Clabeaux.

Dr. Grimsley is a high-volume vascular surgeon in Dallas, Texas, specializing in advanced cerebrovascular interventions. An early adopter of TCAR, he has performed more than 650 TCAR procedures since beginning in 2016. "In this case, my patient had an ulcerated, lipid-laden plaque. The CGuard Prime stent gives me the security of knowing the plaque is covered to prevent embolization."

The CGuard® Prime TransCarotid Stent System is designed to extend the CGuard Prime platform to TCAR, complementing the Company's carotid artery stenting ("CAS") strategy. InspireMD estimates that more than 35,000 TCAR procedures are performed annually. The CGUARDIANS II pivotal trial enrolled 50 patients at 11 U.S. sites and reported 100% acute device success, with no deaths, strokes, myocardial infarctions or stent thrombosis at 30 days.

InspireMD is separately developing SwitchGuard™, its proprietary transcarotid neuroprotection system, currently being evaluated in the CGUARDIANS III study. If approved, SwitchGuard™, together with the CGuard® Prime TransCarotid Stent System, will enable InspireMD to offer a comprehensive TCAR solution to vascular surgeons and other physicians performing TCAR procedures, while expanding the Company's commercial opportunity by addressing both the neuroprotection and carotid stenting components of the procedure.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MicroNet™ mesh technology to make its products the industry standard for carotid stenting by providing outstanding acute results and durable, stroke-free long-term outcomes. InspireMD's common stock is quoted on Nasdaq under the ticker symbol NSPR. We routinely post information that may be important to investors on the Company's website. For more information, please visit www.inspiremd.com.

Forward-looking Statements

This press release contains "forward-looking statements." Forward-looking statements include, but are not limited to, statements regarding InspireMD or its management team's expectations, hopes, beliefs, intentions or strategies regarding future events, future financial performance, strategies, expectations, competitive environment and regulation. Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential", "scheduled" or similar words. In particular, forward-looking statements in this press release include the Company's expectations regarding the U.S. commercialization and commercial opportunity for the CGuard Prime TransCarotid Stent System; the development, clinical evaluation and potential regulatory approval of SwitchGuard; the potential for SwitchGuard and the CGuard Prime TransCarotid Stent System to provide a comprehensive TCAR solution; the Company's ability to compete effectively in the carotid stenting market and increase adoption of its products; and expectations regarding market penetration, commercialization, revenue growth and future operating performance. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company's control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with the voluntary U.S. recall of the CGuard Prime 135 cm delivery system, including current and future costs associated with the recall, including refunds or inventory write-off costs and other remediation costs, loss of sales and customers due to the recall or otherwise, our ability to effectively implement enhancements to CGuard Prime 135 cm delivery system, potential actions by regulators or other governmental entities associated with the recall, potential claims and lawsuits by customers and patients, including class action product liability lawsuits, other operational impacts and consequences of the recall, such as business disruption and distraction of management and other key employees; the Company's history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of its liquidity to pursue its complete business objectives, and substantial doubt regarding its ability to continue as a going concern; the Company's need to raise additional capital to meet its business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute out stockholders' ownership interests; the clinical development, commercialization and market acceptance of the Company's products; whether the clinical trial results for the Company's products will be predictive of real-world results; an inability to secure and maintain regulatory approvals for the sale of the Company's products; negative clinical trial results or lengthy product delays in key markets; the Company's ability to maintain compliance with the Nasdaq listing standards; the Company's ability to generate significant revenues from its products; estimates of the Company's expenses, future revenues, capital requirements and its needs for and ability to access sufficient additional financing, including any unexpected costs or delays in the ongoing commercial launch of its products; the Company's dependence on a single manufacturing facility and its ability to comply with stringent manufacturing quality standards and to increase production as necessary; the risk that the data collected from the Company's current and planned clinical trials may not be sufficient to demonstrate that its technology is an attractive alternative to other procedures and products; intense competition in the Company's industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than it does; entry of new competitors and products and potential technological obsolescence of the Company's products; inability to carry out research, development and commercialization plans; loss of a key customer or supplier; technical problems with the Company's research and products and potential product liability claims; product malfunctions; price increases for supplies and components; whether access to the Company's products is achieved in a commercially viable manner and whether its products receive adequate reimbursement by governmental and other third-party payers; the Company's efforts to successfully obtain and maintain intellectual property protection covering its products, which may not be successful; adverse federal, state and local government regulation, in the United States, Europe or Israel and other foreign jurisdictions; the fact that the Company conducts business in multiple foreign jurisdictions, exposing it to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction; security, political and economic instability in the Middle East that could harm the Company's business, including due to the current security situation in Israel; current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk; and changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements and the impact of such policies on the Company, its customers and suppliers, and the global economic environment. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's web site at http://www.sec.gov. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

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