InspireMD Announces FDA Approval of the CGuard® Prime TransCarotid Stent System for Transcarotid Artery Revascularization (TCAR) Procedures

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- Approval doubles the CGuard Prime platform's total addressable market in the U.S. with additional access to over 35,000 TCAR procedures annually –

- Approval supported by CGUARDIANS II pivotal trial data, which demonstrated 100% acute device success and zero death, stroke, myocardial infarction or stent thrombosis reported at 30 days -

MIAMI, Nov. 12, 2026 (GLOBE NEWSWIRE) -- InspireMD, Inc. (Nasdaq: NSPR) ("InspireMD" or the "Company"), developer of the CGuard® Prime carotid stent system for the prevention of stroke, today announced that the U.S. Food and Drug Administration ("FDA") has approved the Company's Premarket Approval ("PMA") Supplement for the CGuard® Prime TransCarotid Stent System for use in transcarotid artery revascularization ("TCAR") procedures.

The approval allows physicians in the U.S. to use the CGuard® Prime TransCarotid Stent System, which features an 80 cm delivery system, in transcarotid artery revascularization ("TCAR") procedures when used in conjunction with an embolic protection system specified in the labeling. This gives physicians performing TCAR procedures access to the CGuard Prime stent and its proprietary MicroNet™ technology, a permanent protective micromesh that covers the self-expanding nitinol stent.

"Today's approval is a major milestone for InspireMD and for the physicians and patients who may benefit from TCAR as a treatment option for carotid artery disease," said Marvin Slosman, Chief Executive Officer of InspireMD. "This approval extends our CGuard implant to TCAR procedures and is expected to provide a strong near-term growth driver for InspireMD. We believe InspireMD is the first and only company to approach carotid revascularization and stroke prevention with both CAS and TCAR delivery options and an implant-first mission, and we view this TCAR approval as an incredibly important step in advancing our leadership in this field. We look forward to providing patients and physicians with this next-generation stent, which we believe delivers unmatched clinical results."

The approval of the CGuard® Prime TransCarotid Stent System is supported by data from the Company's CGUARDIANS II pivotal trial. This prospective, multicenter, single-arm U.S. study enrolled 50 pivotal patients across 11 investigational sites and evaluated the CGuard® Prime TransCarotid Stent System platform with TCAR using the FDA-cleared ENROUTE Transcarotid Neuroprotection System ("NPS") in a high-surgical-risk population. At 30 days, the study achieved 100% acute device success, with no deaths, strokes, myocardial infarctions, or stent thrombosis reported, and complete stent patency observed in evaluable subjects. The availability of the CGuard® Prime TransCarotid Stent System with an existing FDA-cleared NPS allows InspireMD to enter the TCAR market independently of the Company's ongoing development of its proprietary SwitchGuard™ NPS. SwitchGuard is an investigational device and is not available for sale in the United States.

"TCAR has become an increasingly important technique for carotid revascularization in the U.S., and we believe the availability of CGuard Prime for TCAR gives physicians a differentiated stent option designed around sustained embolic protection," said Patrick J. Geraghty, M.D., Professor of Surgery and Radiology at Washington University School of Medicine in St. Louis and co-lead investigator of the CGUARDIANS II study. "The ability to combine CGuard's MicroNet technology with transcarotid access and existing flow-reversal neuroprotection provides physicians with an important new option for treating patients with carotid artery disease."

With more than 35,000 TCAR procedures performed annually in the United States, the approved TCAR indication doubles the CGuard Prime platform's total addressable market by extending its use beyond CAS procedures. Together, TCAR and CAS represent approximately 75,000 annual carotid stenting procedures in the United States, based on Company estimates.

The approval also represents an important step in InspireMD's broader TCAR strategy. Initially, the CGuard® Prime TransCarotid Stent System can be used in TCAR procedures with an existing FDA-cleared embolic protection system as specified in the labeling. The Company has developed a full suite of TCAR platform devices including SwitchGuard, its next generation transcarotid NPS, which is being evaluated in the CGUARDIANS III pivotal trial that is currently enrolling. If cleared by the FDA, SwitchGuard is expected to complement the CGuard® Prime TransCarotid Stent System and provide InspireMD with a fully integrated proprietary carotid stent and neuroprotection platform for TCAR procedures, along with a proprietary micro puncture access kit expanding the Company's opportunity to capture value across the full TCAR procedure.

Indication for Use

The CGuard® Prime TransCarotid Stent System, when used in conjunction with an embolic protection system specified in the labeling, is indicated for improving carotid luminal diameter in patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization and meet the criteria specified in the labeling. Use of the device carries risks, including

stroke, death, myocardial infarction, stent thrombosis or occlusion, vessel dissection and access-site complications. Rx only. Refer to the Instructions for Use for complete indications, contraindications, warnings, precautions and potential adverse events.

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 listed 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 anticipated commercial launch and timing of sales of the CGuard Prime 80 cm stent system for TCAR procedures, the Company's estimates of the size of the TCAR and CAS markets and its addressable market, the Company's expectations regarding enhancements to the CGuard Prime 135 cm delivery system, the Company's expectations regarding the CGUARDIANS III pivotal trial and potential FDA clearance of SwitchGuard; the Company's ability to compete effectively in the carotid stenting market with both TCAR and CAS delivery systems and increase adoption of its products; expectations regarding market penetration, commercialization, revenue growth and future operating performance; and the Company's strategic priorities, growth plans and future business prospects. 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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