InspireMD Announces First Patient Enrolled in the CGUARDIANS III Pivotal Study of the SwitchGuard Neuro Protection System for Use in TCAR Procedures

June 8, 2026

MIAMI, June 08, 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 first patient has been enrolled in the CGUARDIANS III pivotal study of its SwitchGuard neuro protection system ("NPS"), for use with its CGuard Prime 80 cm stent platform, in transcarotid artery revascularization ("TCAR") procedures. The patient was enrolled by Dr. Patrick Muck at Good Samaritan Hospital, part of the TriHealth System in Cincinnati, Ohio.

Dr. Muck and Dr. Patrick Geraghty, professor of surgery and radiology, section of vascular surgery at Washington University School of Medicine in St. Louis, MO, have agreed to act as global co-principal investigators for the CGUARDIANS III trial.

Marvin Slosman, Chief Executive Officer of InspireMD, commented, "The initiation of the CGUARDIANS III pivotal study represents an important milestone in our quest to offer the full TCAR toolkit capable of addressing the estimated 70,000 TCAR procedures that will be performed annually in the U.S. by 2030. Our SwitchGuard NPS, together with our best-in-class CGuard Prime stent system, represents a meaningful advancement in patient safety and stroke prevention with unmatched clinical outcomes. I would like to thank Drs. Muck and Geraghty, as well as the other investigators, who will ensure a rigorous yet efficient evaluation of these cutting-edge carotid stenting technologies."

"Building on the strong clinical momentum established by the CGUARDIANS II study of CGuard Prime 80 cm with FDA-cleared neuro protection systems, we are excited to advance into the next phase of innovation with the CGUARDIANS III study of the SwitchGuard NPS," added Dr. Muck. "SwitchGuard represents a natural evolution of InspireMD's commitment to achieving the best clinical outcomes in carotid artery disease, particularly in the growing adoption of TCAR procedures. By combining the proven performance of CGuard Prime with next-generation neuro protection, we aim to further enhance procedural safety while reducing stroke risk and providing physicians with a comprehensive solution tailored to the needs of their patients. We believe SwitchGuard, if approved, has the potential to set a new standard of care in carotid revascularization."

CGUARDIANS III is a prospective, multi-center, single-arm, pivotal study that will enroll approximately 103 subjects. The objective of the study is to evaluate the safety and efficacy of the SwitchGuard NPS in providing cerebral embolic protection during TCAR procedures using the CGuard Prime 80 cm stent system for the treatment of carotid artery stenosis in patients at high risk for complications from carotid endarterectomy ("CEA").

For additional information: https://clinicaltrials.gov/study/NCT07277296

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 estimates of market size and growth projections for TCAR procedures and the carotid stenting market, and the Company's ability to enroll, complete and obtain favorable results from its CGUARDIANS III pivotal study and any other ongoing or planned clinical trials. 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 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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