# InspireMD Announces 30-Day Results from the CGUARDIANS II Clinical Trial of the CGuard Prime 80 cm Implant for Use in TCAR Procedures

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## PMA supplement under FDA review with potential approval in H2 2026, potentially expanding the Company's addressable market to include TCAR in addition to CAS carotid stenting procedures

MIAMI, June 11, 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 30-day outcomes from the CGUARDIANS II clinical trial of the CGuard Prime 80cm implant for use in transcarotid artery revascularization (TCAR) procedures. InspireMD anticipates potential approval of the CGuard Prime 80 cm stent implant in the second half of this year.

Key 30-day outcomes observed in the CGUARDIANS II trial include:

- Acute device success was achieved in 100% (50/50) of patients;
- No deaths, strokes, or myocardial infarctions were reported within 30 days;
- No stent thrombosis was observed within 30 days;
- Complete stent patency observed at 30 days in evaluable subjects.

Dr. Patrick J. Geraghty, professor of surgery and radiology at Washington University School of Medicine in St. Louis and co-lead investigator of the CGUARDIANS II study, commented, "The 30-day results observed in the CGUARDIANS II trial suggest that the CGuard Prime 80 cm stent may deliver exceptional safety and efficacy when used with a TCAR approach. Notably, the 100% acute device success rate with zero major adverse events has the potential to make CGuard Prime the gold standard implant for high-risk patients undergoing TCAR procedures. I look forward to incorporating it into my own practice, if approved."

"We believe the 30-day CGUARDIANS II results represent a significant achievement in our quest to tap into the large and growing TCAR market," said Marvin Slosman, CEO of InspireMD. "Together with our recently initiated CGUARDIANS III clinical trial of our proprietary SwitchGuard neuroprotection system, we potentially have line-of-sight to offering the full TCAR toolkit, subject to regulatory review and approval, leveraging our best-in-class CGuard Prime Carotid Stent System with its unmatched clinical outcomes, for the more than 35,000 TCAR procedures that are performed in the U.S. every year."

CGUARDIANS II is a prospective, multi-center, single-arm pivotal study that enrolled 50 patients across 11 trial sites. The objective of the study is to evaluate acute device success and technical success of the CGuard Prime 80 cm when used in conjunction with the FDA-cleared ENROUTE TCAR neuro-protection system in patients considered at high risk for adverse events from carotid endarterectomy.

Regulatory Disclaimer: The CGuard Prime Carotid Stent System 80 cm is an investigational device in the United States and is limited by federal law to investigational use. InspireMD submitted a Premarket Approval (PMA) Supplement to the U.S. Food and Drug Administration (FDA) which is currently under review.

**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 expectations regarding potential FDA approvals for CGuard Prime Carotid Stent System 80 cm implant for use in TCAR procedures. 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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