InspireMD Announces FDA Approval for CGuard® Prime Carotid Stent System for the Prevention of Stroke

June 24, 2025

Miami, Florida — June 24, 2025 (GLOBE NEWSWIRE) – InspireMD, Inc. (the "Company") (Nasdaq: NSPR), 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 granted premarket application (PMA) approval of the CGuard Prime Carotid Stent System in the United States.

The PMA approval is backed by best-in-class evidence from the Company's C-GUARDIANS pivotal trial, first presented at the Leipzig Interventional Course (LINC) in May 2024. The study, which enrolled 316 patients across 24 sites in the United States and Europe, evaluated the safety and efficacy of CGuard Prime for treating carotid artery stenosis. CGuard Prime demonstrated the lowest 30-day (0.95%) and

1-year (1.93%) primary endpoint major adverse event rates of any pivotal study of carotid intervention.

"The C-GUARDIANS clinical trial provides strong scientific evidence to support the neuro-protective benefits of the next generation MicroNet™ mesh technology of the CGuard Prime Carotid Stent System and results are consistent with the large body of evidence from outside of the United States with this device", said Dr. D. Chris Metzger, System Vascular Chief at OhioHealth. "As U.S. Primary Investigator for this pivotal IDE trial, I am proud of the scientific rigor and integrity of the data, which demonstrates the lowest event rates (stroke, death and MI to 30 days and ipsilateral stroke at 1 year) ever reported in any trial of carotid revascularization. These excellent results were in patients who were at high risk for carotid endarterectomy, a quarter of whom were symptomatic. CGuard Prime now offers an important frontline, proven technology for treatment of United States patients with obstructive carotid artery disease, and continued benefits to patients worldwide."

"I am proud to announce the PMA approval of CGuard Prime, our best-in-class carotid stent system. This is a pivotal milestone for the Company after many years of commitment to bringing this innovative stent platform to patients in the United States," said Marvin Slosman, Chief Executive Officer of InspireMD. "The significance of CGuard Prime to the shift toward less invasive carotid artery revascularization is tremendous. Our approval marks a true breakthrough in the treatment of carotid disease. Our innovation is built around the protective MicroNet mesh barrier providing durable protection and preventing post procedural events, a unique and next generation advancement in the carotid field. With over 65,000 implants sold to date and studies in over 2,000 patients, CGuard Prime offers an established and tested advancement to patient care. We are grateful to the many who have contributed to this approval, including all of our trial investigators and investors. We look forward to making this technology available to all who can benefit with an immediate and aggressive U.S. launch."

The Company's announcement of FDA approval of the CGuard Prime Carotid Stent System triggers the second of four milestone-driven warrant tranches pursuant to the private placement financing of up to $113.6 million announced in May 2023. Gross proceeds from this warrant tranche are expected to be $17.9M if exercised in full. Proceeds, if any, will be used to support the imminent commercial launch of the CGuard Prime Carotid Stent System in the United States, initiating new regulatory pathways for advanced applications of our CGuard stent platform, and developing new products, while at the same time continuing to develop our business outside of the United States. Warrant holders include Marshall Wace, OrbiMed, Rosalind, Nantahala, Soleus, Velan, and certain InspireMD Board members.

About CGuard Prime

The CGuard Prime Carotid Stent System is a novel mesh-covered carotid stent designed to improve patient safety through sustained embolic protection. CGuard Prime combines the largest open-cell frame of available carotid stents with the smallest mesh pore size, preventing plaque protrusion through the stent, for lasting embolic protection demonstrated beyond five years.

About C-GUARDIANS

The C-GUARDIANS clinical trial evaluated the safety and efficacy of the CGuard Carotid Stent System for the treatment of carotid artery stenosis. The study enrolled 316 patients across 24 trial sites in the United States and Europe.

The trial included both symptomatic and asymptomatic patients undergoing carotid artery stenting (CAS). The primary endpoint includes the composite of the following: incidence of the following major adverse events: death (all- cause mortality), all stroke, or myocardial infarction (DSMI) through 30-days post-index procedure, based on the Clinical Events Committee (CEC) adjudication or ipsilateral stroke from 31-365-day follow-up, based on CEC adjudication. The performance goal was considered to have been met if the upper bound of the two-sided 95% confidence interval calculated from the observed primary endpoint rate is <11.6% and the p-value is <0.025.

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 our website. For more information, please visit 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, including potential U.S. commercial launch and expectations regarding the exercise of any warrants. 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. 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 our history of recurring losses and negative cash flows from operating activities; substantial doubt about our ability to continue as a going concern; significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives; our need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute out stockholders' ownership interests; market acceptance of our products; an inability to secure and maintain regulatory approvals for the sale of our products; negative clinical trial results or lengthy product delays in key markets; our ability to maintain compliance with the Nasdaq listing standards; our ability to generate revenues from our products and obtain and maintain regulatory approvals for our products; our ability to adequately protect our intellectual property; our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary; the risk that the data collected from our current and planned clinical trials may not be sufficient to demonstrate that our technology is an attractive alternative to other procedures and products; intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do; entry of new competitors and products and potential technological obsolescence of our products; inability to carry out research, development and commercialization plans; loss of a key customer or supplier; technical problems with our research and products and potential product liability claims; product malfunctions; price increases for supplies and components; insufficient or inadequate reimbursement by governmental and other third-party payers for our products; our efforts to successfully obtain and maintain intellectual property protection covering our 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 we conduct business in multiple foreign jurisdictions, exposing us 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; the escalation of hostilities in Israel, which could impair our ability to manufacture our products; and current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk. 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 https://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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