InspireMD Announces U.S. Commercial Launch of CGuard® Prime Carotid Stent System for the Prevention of Stroke

July 9, 2025

Miami, Florida — July 9, 2025 (GLOBE NEWSWIRE) – InspireMD, Inc. (Nasdaq: NSPR), developer of the CGuard Prime carotid stent system for the prevention of stroke, today announced the official commercial launch of the CGuard Prime carotid stent system in the U.S., following its premarket application (PMA) approval from the U.S. Food and Drug Administration (FDA).

The CGuard Prime was engineered specifically to minimize both early and late embolism risk by effectively trapping potential emboli against the arterial wall while preserving external carotid artery perfusion. This innovative device features three key advantages: First, a dual layer design that combines the largest open-cell frame with the smallest mesh pore size available. Second, the MicroNet™, a bio-stable mesh crafted from a single 20 µm Polyethylene Terephthalate (PET) strand that traps and seals thrombus and plaque against the vessel wall to prevent embolization. Third, SmartFit™ technology eliminates the need for tapered versions while ensuring precise vessel wall apposition.

“Our U.S. commercial launch marks a pivotal milestone in InspireMD’s expansion history, having already secured double-digit market share across more than 30 countries,” said Marvin Slosman, Chief Executive Officer of InspireMD. “We’ve spent the past year meticulously preparing for this moment, assembling a world-class commercial team comprised of industry veterans with deep expertise and longstanding relationships. Backed by this all-star team and a robust operational infrastructure, we are poised to execute a highly impactful U.S. launch. We’re incredibly grateful to everyone who contributed to making this possible and couldn’t be more excited about the road ahead.”

“Treating patients with the CGuard Prime system is incredibly meaningful, both personally, for the advancement of innovation at OhioHealth, and for the field of carotid intervention as a whole,” said Dr. D. Chris Metzger, System Vascular Chief at OhioHealth. “CGuard’s unique design makes a real difference in addressing the complexities of carotid artery disease, offering enhanced embolic protection without compromising deliverability. My experience using the system—both in clinical trials and now in practice —reinforces how much demand there is for safer, less invasive alternatives, particularly for patients at higher risk of stroke. This technology represents an important advancement in how we approach stroke prevention in the U.S.”

“Our team at Ballad Health is thrilled to have contributed to the journey of this novel next generation carotid device. From initiating the first C-GUARDIANS enrollments in 2021 and leading enrollment throughout the trial to supporting the first commercial case by Dr. Chris Metzger, we have been a crucial contributor to the full life cycle of this technology to date. Our efforts reflect the commitment of the Ballad Health System to advancing innovation to improve patient care and offering the latest in medical breakthrough technologies,” shared Alan Levine, Chairman and CEO, Ballad Health.

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 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 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, 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 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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