InspireMD Announces Publication of the C-GUARDIANS Pivotal Trial Manuscript in the Journal of the American College of Cardiology (JACC)

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The CGuard® Prime Carotid Stent System demonstrated the lowest 30-day and 1-year primary endpoint major adverse event rates of any pivotal study of carotid stenting (CAS)

MIAMI, Jan. 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 results from the Company's C-GUARDIANS pivotal trial have now been published in the *Journal of the American College of Cardiology* (JACC). The data demonstrate the safety and efficacy of carotid artery stenting (CAS) with the Company's MicroNet™ covered stent in patients with asymptomatic carotid stenosis.

As shown at VIVA in late 2023 and LINC in mid-2024, C-GUARDIANS demonstrated low rates of disabling stroke or myocardial infarction (DSMI) through 30 days and low ipsilateral stroke rates through one year, with no unexpected device-related adverse events reported. This pivotal trial showed historically low event rates in patients with obstructive carotid disease at high risk for complications with carotid endarterectomy (CEA). The cohort included 25% symptomatic patients, comparing favorably with similar patients treated with all forms of carotid revascularization in clinical trials. The published study is available here.

"The C-GUARDIANS results are exceptional, with a 30-day DSMI rate of just 0.95% and a one-year ipsilateral stroke rate of 1.93%, which are the lowest reported in high-risk patients," said Dr. Chris Metzger, M.D., Interventional cardiologist and endovascular interventionalist at Ballad Health, and lead investigator of the C-GUARDIANS trial. "What's particularly noteworthy is that we achieved these outcomes in a cohort that included 25% symptomatic patients, a group traditionally at elevated risk. The data make a compelling case for the CGuard® Prime's MicroNet™ technology as a potential next-generation standard of care."

"For interventionalists, the C-GUARDIANS publication marks an important step forward in the industry shift toward a stent-system approach to carotid revascularization," said Peter Soukas, M.D., Chief Medical Advisor of InspireMD. "Clinicians are looking for proven technologies that expand patient eligibility without compromising outcomes. The trial data offer strong clinical validation for wider use of CGuard® Prime, and we expect the JACC publication to drive further physician awareness and engagement."

"This publication in JACC validates years of innovation and clinical rigor behind CGuard® Prime, and has the potential to accelerate our ongoing efforts to bring CGuard® Prime to the thousands of U.S. patients who can now benefit from this breakthrough technology," said Marvin Slosman, Chief Executive Officer of InspireMD. "With peer-reviewed evidence now published in one of the industry leading journals, we are even better positioned to drive adoption and deliver meaningful value to patients, physicians, and healthcare systems."

CGuard® Prime is FDA PMA-approved for the treatment of carotid artery stenosis in the United States.

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 U.S. 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, or ipsilateral stroke from 31-365-day follow-up, based on the Clinical Events Committee (CEC) independent adjudication. The performance goal will be 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. The study was published in the American College of Cardiology (JACC) on December 2, 2025.

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.

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