# InspireMD Announces First Patient Enrolled in U.S. Registration Trial for MGuard™ Prime EPS

PR Newswire

InspireMD, Inc. (NYSE MKT: NSPR) ("Inspire" or the "Company"), a leader in embolic protection stents, said the first patient has been enrolled in the Master II IDE clinical trial to evaluate the safety and effectiveness of the MGuard™ Prime Embolic Protection Stent (EPS) in patients suffering from ST Elevation Myocardial Infarction (STEMI).

The multi-center, randomized trial is expected to include up to 70 sites in the U.S. and Europe and as many as 1,114 patients. The results are intended to support the Company's Investigational Device Exemption (IDE) application with the U.S. Food and Drug Administration (FDA) to market the MGuard™ Prime MicroNet™ covered coronary stent system in the U.S.

The trial has two co-primary endpoints: superiority in complete ST resolution and non-inferiority in death and target vessel myocardial infarction. In addition, a 356 patient sub-study will be conducted to assess the effect of the MGuard Prime™ EPS on infarct size, as measured by Magnetic Resonance Imaging (MRI).

The trial's principal investigators are Gregg Stone, M.D. of New York Presbyterian Hospital and Columbia University Medical Center in New York City, and Jose P. S. Henriques, M.D. of the Academic Medical Center in Amsterdam.

The first procedure was performed at ZNA Middelheim by Stefan Verheye, M.D. "Distal embolization and no-reflow are severe concerns when treating our STEMI patients. From our experience over the last two years, the MGuard Prime EPS has improved patient outcome and led to brilliant results, thanks to its unique protective mesh," said Dr. Verheye. "I am excited about participating in the MASTER II Trial and enthusiastic about its potential impact on patient care worldwide."

"Enrolling our first patient in MASTER II is a very important milestone for the company. We are committed to advancing patient care through robust clinical research," said Alan Milinazzo, InspireMD's CEO and President. "MASTER II provides another important opportunity for us to demonstrate the safety of MGuard EPS and to validate its effectiveness compared to current standard of care treatment for STEMI patients."

The FDA trial, known as MASTER II (MGuard™ for Acute ST Elevation Reperfusion), is the second in a series of randomized clinical studies intended to validate the safety and effectiveness of the MGuard™ EPS platform and achieve registration with appropriate regulatory authorities worldwide.

InspireMD's MGuard™ EPS technology previously yielded positive results in the

MASTER Trial findings, showing a statistically and clinically significant acute advantage with regard to ST segment resolution. As a result, the MGuard™ EPS may hold the potential to lower the incidence of adverse events and improve the survival of patients suffering from acute myocardial infarction.

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