InspireMD's MGuard Embolic Protection Stent (EPS) Shows Lower Mortality Rate in STEMI Patients at Six Months Compared to Control Group

PR Newswire

PARIS, May 23, 2013 /PRNewswire/ -- InspireMD, Inc., the leader in embolic protection stents, today announced new 6-month results from the MASTER (**M**Guard for **A**cute **ST** **E**levation **R**eperfusion) trial demonstrating that the MGuard Embolic Protection Stent (EPS) outperformed bare metal and drug eluting stents in all-cause mortality in ST segment elevation myocardial infarction (STEMI) patients. Results from the trial were presented at the InspireMD STEMI Symposium at EuroPCR, the official annual meeting of the European Association for Percutaneous Cardiovascular Interventions (EAPCI) taking place in Paris from May 21-24, 2013.

In addition to the symposium, the Company reported that another fourteen presentations and three abstracts highlighting the MGuard EPS technology were presented over the 4-day conference.

With its proprietary micro-net mesh sleeve, MGuard EPS addresses an unmet need by preventing unstable arterial plaque and thrombus (clots) that cause heart attack blockage from breaking off and exacerbating damage.

The MASTER trial achieved its primary endpoint (p value = 0.008), in complete ST-segment resolution at 60-90 min post-procedure (a strong predictor of mortality). Secondary endpoint clinical outcomes continue to show a lower mortality rate with MGuard EPS compared to control (0.5% vs. 2.8%, P=0.06) at 6 months. These findings corroborate the previously announced 30-day results showing that all-cause mortality with MGuard EPS was lower than bare metal and drug eluting stents used as a control (0% vs. 1.9%, P=0.06). Additional 6-month results are available at http://www.inspiremd.com [1].

"The initial MASTER trial results published in the Journal of the *American College of Cardiology*[1] in October 2012 demonstrated the acute benefits of the embolic protection stent, as MGuard EPS outperformed drug-eluting and bare metal stents in complete ST-segment resolution," said Professor Dr. Sigmund Silber , Director of the Heart Center at the Isar Academic Teaching Site of the University of Munich. "The six-month MASTER results highlight the enduring benefits of the MGuard EPS, with a consistent trend in lower mortality."

In the MASTER trial, a total of 433 patients with STEMI presenting within 12 hours of symptom onset undergoing percutaneous coronary intervention were randomized at 50 sites in 9 countries to the MGuard EPS (n = 217) or commercially available bare metal or drug-eluting stents (n = 216).

"The body of positive clinical evidence supporting the use of the MGuardEPS continues to grow," said Alan Milinazzo , President and Chief Executive Officer of InspireMD. "Both the 6-month data and the subgroup analysis presented this week at EuroPCR in Paris, suggest that our technology offers improved embolic protection over the current generation of bare metal and drug eluting stents for the STEMI patient. Advancing embolic protection without requiring physicians to increase procedure time or dramatically change their technique is a major benefit of the MGuard EPS."

Watch the video: https://www.youtube.com/watch?v=EbrhcQMM7YE [2]

Conference Call and Webcast Details

InspireMD will host a conference call and webcast to review 6-month MASTER trial data on Thursday May 23, 2013 at 8:00 ET, 14:00 CET. To access the call, participants should dial the following numbers:

- U.S. and Canada: +1-888-417-8516
- Paris: +33-08-00-90-26-40
- International: +1-719-325-2144

The webcast will be available at http://www.InspireMD.com [3]. An archived webcast will be available for 30 days.

About Stenting and MGuard EPS
Standard stents were not engineered exclusively for heart attack patients. They were also designed for treating stable angina patients whose occlusion contains thrombotic material.

In acute heart attack patients, the plaque or thrombus is unstable and often breaks up as the stent is implanted causing downstream blockages (some of which can be fatal) in a significant portion of heart attack patients.

The MGuard EPS integrates a precisely engineered micro net mesh designed to prevent the unstable arterial plaque and thrombus (clots) that caused the heart attack blockage from breaking off.

While offering superior performance relative to standard stents in STEMI patients with regard to ST segment resolution, the MGuard EPS requires no change in current physician practice - an important factor in promoting acceptance and general use in time-critical emergency settings.

About InspireMD, Inc.
InspireMD's mission is to utilize its proprietary MGuard technology to make its products the industry standard for stents and to provide a superior solution to the key clinical issues of current stenting: embolic showers, restenosis and late stent thrombosis.

InspireMD intends to pursue applications of this technology in coronary, carotid and peripheral artery procedures. InspireMD's common stock is quoted on the NYSE MKT under the ticker symbol NSPR.

MGuard EPS is CE Mark approved. It is not approved for sale in the U.S. by the Food and Drug Administration (FDA) at this time.

1. Stone GW, Abizaid A, Silber S, Dizon JM, Merkely B, Costa RA, Kornowski R, Abizaid A, Wojdyła R, Maehara A, Dressler O, Brener SJ, Bar E, Dudek D.Prospective, Randomized, Multicenter Evaluation of a Polyethylene Terephthalate Micronet Mesh-Covered Stent (MGuard) in ST-Segment Elevation Myocardial Infarction: The MASTER Trial.J Am Coll Cardiol. 2012;60(19):1975-1984

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http://www.mdtmag.com/news/2013/05/inspiremds-mguard-embolic-protection-stent-eps-shows-lower-mortality-rate-stemi-patients-six-months-compared-control-group?qt-video_of_the_day=0

Links:
[1] http://www.inspiremd.com/
[2] https://www.youtube.com/watch?v=EbrhcQMM7YE
[3] http://www.InspireMD.com