INSPIREMD, INC.

FORM 8-K
(Current report filing)

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Sector	Healthcare
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 15, 2014

InspireMD, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-35731	26-2123838
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

321 Columbus Avenue Boston, Massachusetts	02116
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (857) 453-6553

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4 (c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure.

Attached hereto as Exhibit 99.1 is a PowerPoint presentation that Professor Gregg W. Stone, MD, presented on December 15, 2014, at the International Conference for Innovations in Cardiovascular Systems ("ICI") meeting in Tel Aviv, Israel, with respect to the results of InspireMD, Inc.'s MGuard™ Prime EPS MASTER II trial.

The information furnished in this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On December 15, 2014, InspireMD, Inc. issued a press release announcing the recently released results of MGuard™ Prime EPS MASTER II trial and CGuard™ CARENET trial and that the results were presented at the ICI meeting in Tel Aviv, Israel, on December 15, 2014.

A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	2014 ICI Presentation
99.2	Press release dated December 15, 2014

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INSPIREMD, INC.

Date: December 15, 2014

By: /s/ Craig Shore
Name: Craig Shore
Title: Chief Financial Officer

The MASTER II Trial

Comparison of the MGuard Embolic Protection Stent with Standard Stents in Acute Myocardial Infarction

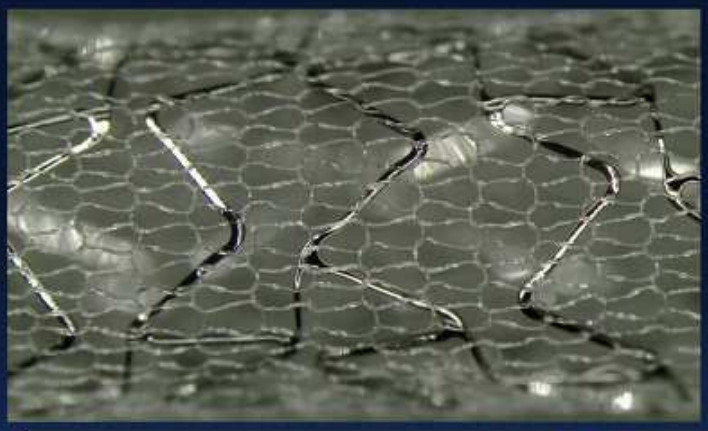
Gregg W. Stone, MD

Columbia University Medical Center
NewYork-Presbyterian Hospital
Cardiovascular Research Foundation

Background

- In the randomized MASTER I trial, among 433 pts with STEMI undergoing primary PCI, treatment with the MGuard stent compared to standard BMS/DES resulted in improved rates of TIMI-3 flow and ST-segment resolution, a trend toward lower mortality at 30-days and 1 year, but greater rates of restenosis and TLR
- The MASTER II trial was therefore designed as the US pivotal approval trial for the MGuard Prime embolic protection stent

The MGuard and MGuard Prime Embolic Protection Stent (EPS)



	MGuard	MGuard Prime
Metallic frame	316L stainless steel	L605 cobalt chromium
Strut width	100 µm	80 µm
Crossing profile	1.1 – 1.3 mm	1.0 – 1.2 mm
Shaft dimensions	0.65 – 0.86 mm	0.65 – 0.86 mm
Mesh sleeve	PET**	PET**
- Fiber width	20 µm	20 µm
- Net aperture size	150 - 180 µm	150 - 180 µm

*InspireMD, Tel Aviv, Israel; **Polyethyleneterephthalate

MGUARD for Acute ST Elevation Reperfusion

The MASTER I Trial

STEMI with symptom onset within 12 hours at
433 pts at 50 sites in 9 countries

R

Stratified by infarct vessel
and thrombus aspiration

PCI with BMS or DES

PCI with MGuard

Follow-up: 30 days, 6 months, 1 year

Primary endpoint: ST-segment resolution at 60-90 minutes

Substudies:

Cardiac MRI: 60 pts (30 pts in each arm) at 3-5 days

Angio FU: 50 pts in MGuard arm at 13 months

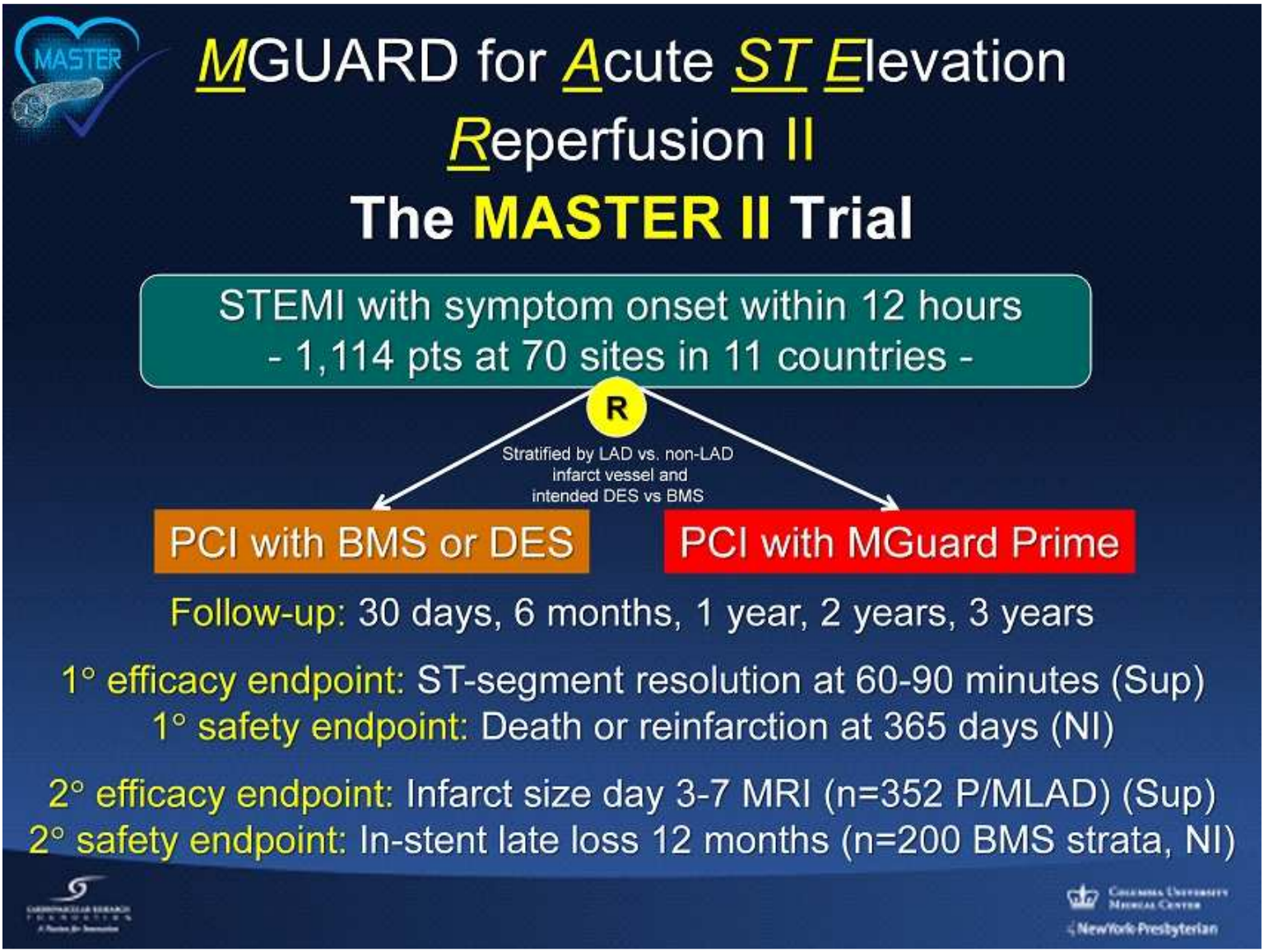
Stone GW et al. J Am Coll Cardiol 2012;60:1975–84

MASTER I Results

Stone GW et al.
JACC 2012;60:1975–84

	MGuard stent (n=217)*	Control stent (n=216)**	*P* value
Device success†	95.9%	99.1%	0.03
TIMI-3 flow achieved	91.7%	82.9%	0.006
Angiographic success‡	91.7%	82.4%	0.004
Complete ST-segment resolution	57.8%	44.7%	0.008
Infarct size (%LV; n=59)	13.3 [7.9, 25.0]	16.6 [10.0, 22.6]	0.48
30-day events			
- Death	0%	1.9%	0.06
- MACE (CD, MI, ID-TLR)	1.8%	2.3%	0.75
1-year events	19 [15, 24]	20 [15, 24]	0.64
- Death	1.0%	3.3%	0.09
- TLR	8.6%	0.9%	0.0003
- MACE (CD, MI, ID-TLR)	9.1%	3.3%	0.02
- Stent thrombosis (def/prob)	2.3%	0.9%	0.26

*191 (88%) MGuard, 26 MGuard Prime; **39.8% DES; †<50% final residual stenosis using only the randomized stent; ‡< 50% final residual stenosis and TIMI-3 flow


MASTER
MGUARD for Acute ST Elevation Reperfusion II
The MASTER II Trial
STEMI with symptom onset within 12 hours
- 1,114 pts at 70 sites in 11 countries -
R
Stratified by LAD vs. non-LAD infarct vessel and intended DES vs BMS
PCI with BMS or DES
PCI with MGuard Prime
Follow-up: 30 days, 6 months, 1 year, 2 years, 3 years
1° efficacy endpoint: ST-segment resolution at 60-90 minutes (Sup)
1° safety endpoint: Death or reinfarction at 365 days (NI)
2° efficacy endpoint: Infarct size day 3-7 MRI (n=352 P/MLAD) (Sup)
2° safety endpoint: In-stent late loss 12 months (n=200 BMS strata, NI)
NewYork-Presbyterian

MASTER II
Principal Inclusion Criteria

- Symptoms consistent with STEMI between 30 mins and 12 hrs of symptom onset
- ≥2 mm of ST-segment elevation in ≥2 contiguous leads
- TIMI 2 or 3 flow restored either spontaneously, by aspiration or pre-dilatation
- PCI of a single de novo lesion with RVD ≥2.75 to ≤4.0 mm and length ≤24 mm (capable of being covered by a single study stent)

MASTER II
Principal Exclusion Criteria

- LBBB, paced rhythm, etc.
- Prior PCI w/i 30d or planned non-TV PCI w/i 7d or planned TV-PCI w/i 12 months
- Cardiogenic shock or CPR
- ≥50% left main stenosis present
- Infarct lesion ostial or bifurcation with ≥2.0 mm sidebranch
- Target vessel or infarct lesion excessively tortuous, angulated or with moderate to heavy calcification
- Prior stent within target vessel

MASTER II Study Organization

Principal investigator:	Gregg W. Stone
Co-principal investigator:	Jose PS Henriques
Steering committee:	Gregg W. Stone, Jose PS Henriques, Eli Bar, Donald Cutlip, Ori Ben-Yehuda
Data monitoring:	Medpace Medical Device, Minneapolis, MN, USA; MEDPASS, Paris, France and KCRI, Krakow , Poland
Data management and analysis:	Cardiovascular Research Foundation (CRF), NY, NY; Ori Ben-Yehuda (Director), Melissa Nichols
Event adjudication:	CRF; Sorin Brener (Director), Alejandra Guerchicoff (Co-director)
ECG core laboratory:	CRF; Jose Dizon (Director)
Angio core laboratory:	CRF; Philippe Genereux (Director)
MRI core laboratory:	CRF; Steve Wolff (Director), Akiko Maehara, (Co-director)
DSMB:	Bernard Gersh (Chair), David Faxon, Stuart Pocock
Sponsor and funding:	InspireMD, Tel Aviv, Israel

MASTER II Enrollment

1. Enrollment was voluntarily suspended on April 30th, 2014 after 310 patients had been randomized at 46 international sites because of a higher than expected rate of stent dislodgement with the MGuard Prime
2. No patient in MASTER II experienced an endpoint event due to a stent dislodgement
3. The issue has been addressed with a manufacturing change; device re-approval has been granted in US for IDE and EU for commercial use
4. Sponsor elected to terminate enrollment because of slow recruitment in the BMS strata, especially in US

MASTER II Top 12 Enrolling Sites

Between July 25th, 2013 and April 29th, 2014,
310 pts were randomized at 46 sites in 12 countries

1. Peep Laanmets, North Estonia Regional Hospital, Tallinn, Estonia	22
2. Andreas Baumbach, Bristol Heart Institute, Bristol, UK	21
3. Marek Kondys, III Oddzial Kardiologii, Dabrowa Gornicza, Poland	20
4. Niels van Royen, VUMC Amsterdam, Amsterdam, Netherlands	16
5. Martin Mates, Na Homolce Hospital, Prague, Czech Republic	15
6. Jan Peruga, Medical University, Lodz, Poland	14
7. Aleksander Zurakowski, American Heart of Poland, Chrzanow, Poland	13
8. Giovanni Amoroso, Onze Lieve Vrouwe Gasthuis, Amsterdam, NL	12
9. Jose P.S. Henriques, Academic Medical Center, Amsterdam, NL	11
10. Adam Witkowski, Institute of Cardiology, Warszaw, Poland	11
11. Christopher Malkin, Leeds General Infirmary, Leeds, UK	11
12. Jan Pattanayak, Asheville Cardiology Associates, Asheville, NC, US	10

MASTER II Baseline Characteristics

	MGuard Prime (n=155)		Control stent (n=155)
Age (years)	60 [52, 66]	*	62 [55, 70]
Male	79.4%		73.5%
Hypertension	40.6%		49.7%
Hyperlipidemia	31.6%		28.4%
Diabetes mellitus	13.5%		18.1%
Cigarette smoking	52.3%		45.5%
Prior MI	7.1%		6.5%
Prior PCI	7.1%		5.2%
Symptoms to device, mins	172 [130, 322]		170 [122, 253]
Infarct artery = LAD	36.8%		37.4%
Baseline TIMI flow = 0/1**	67.8%		71.6%
Baseline RVD, mm**	3.03 [2.73, 3.31]		2.97 [2.68, 3.35]
Baseline DS %**	100.0 [83.8, 100.0]		100.0 [85.1, 100.0]

*P=0.04; **core lab

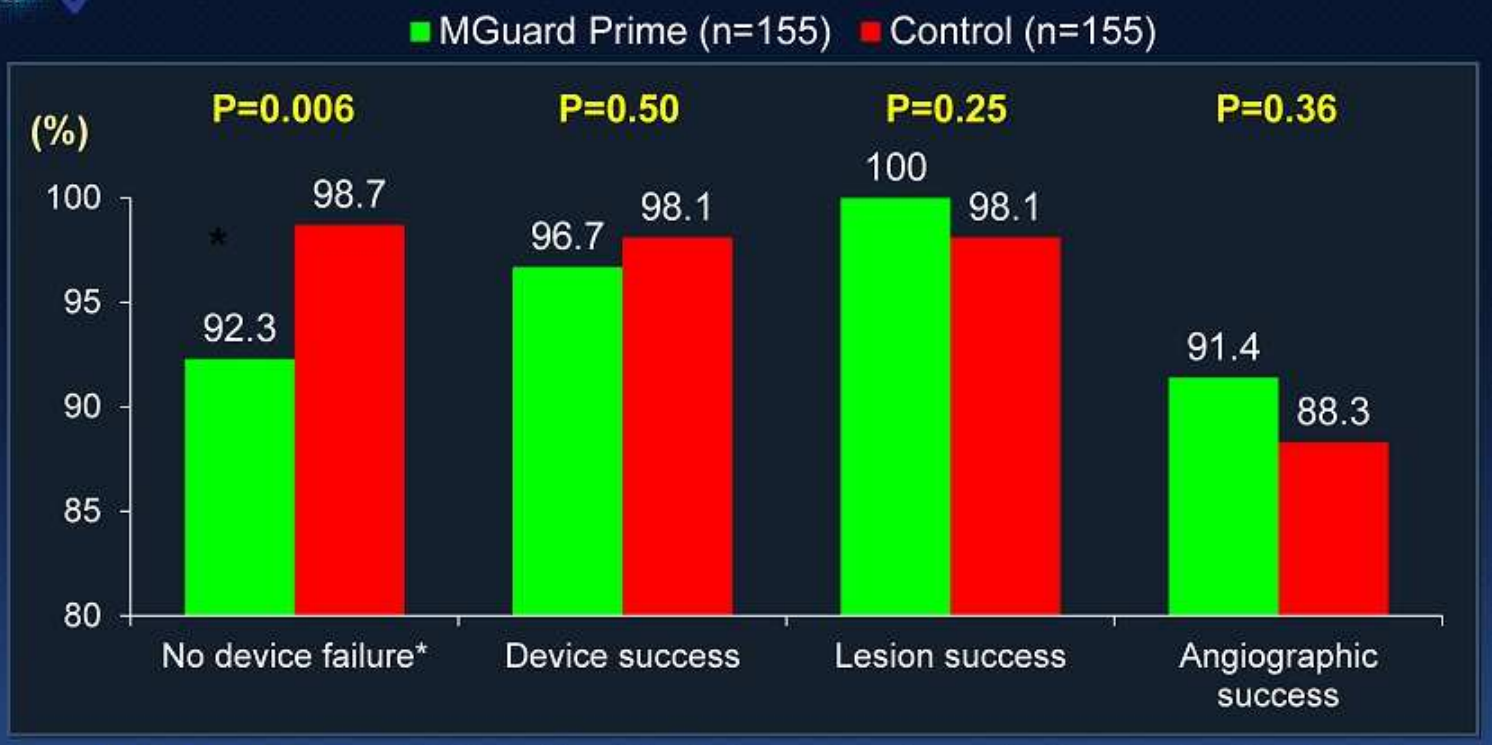
MASTER II Procedural Medications

	MGuard Prime (n=155)	Control stent (n=155)	*P* value
Anticoagulation, peri-procedural			
– Unfractionated heparin	70.1%	67.8%	0.65
– Glycoprotein IIb/IIIa inhibitor	45.5%	53.3%	0.17
– Bivalirudin	37.0%	31.6%	0.32
Anti-platelet agents, discharge			
– Aspirin	98.7%	96.7%	0.28
– ADP antagonists	98.7%	98.0%	0.68
– Clopidogrel	44.8%	45.4%	0.92
– Prasugrel	29.2%	31.6%	0.65
– Ticagrelor	33.1%	33.6%	0.94

MASTER II Procedures

	MGuard Prime (n=155)	Control stent (n=155)	*P* value
Aspiration performed	60.6%	62.6%	0.73
Balloon pre-dilatation performed	49.7%	34.8%	0.008
Direct stenting	13.5%	18.1%	0.28
≥1 stent implanted	99.4%	99.4%	1.00
≥2 stents implanted	9.7%	14.2%	0.22
Stent type			
– MGuard Prime	96.8%	0%	<0.0001
– Bare metal stent	3.9%	20.1%	<0.0001
– Drug-eluting stent	3.2%	80.5%	<0.0001
Total stent length, mm	18 [18, 23]	23 [18, 28]	0.08
Post stent dilatation performed	37.4%	33.8%	0.50
Maximal device size, mm	3.5 [3.0, 4.0]	3.5 [3.0, 3.5]	0.38
Maximal dilatation pressure, atm	16 [14, 18]	16 [14, 18]	0.12

MASTER II Device Success



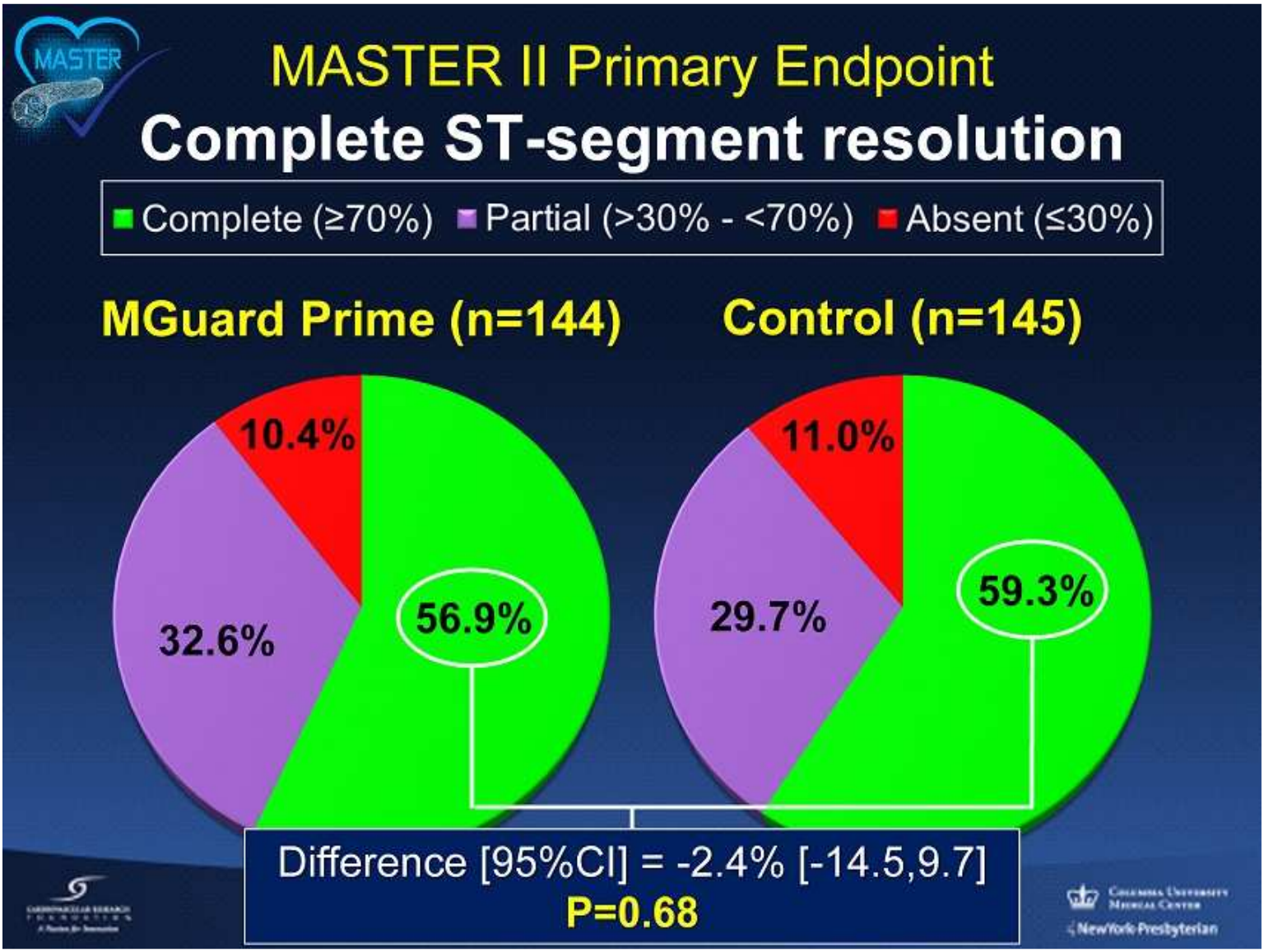
Device success: <50% final residual stenosis using only the randomized stent
Lesion success: <50% final residual stenosis using any percutaneous method
Angiographic success: <50% final residual stenosis and final TIMI 3 flow

*MGuard Prime arm: failure to cross lesion (4 [2.6%]); stent dislodgement (5 [3.2]%); failure to deploy or deployment at unintended site (5 [3.2]%). Control arm: failure to cross lesion (1 [0.6%]); other (1 [0.6%])

MASTER II Procedural Results

	MGuard Prime (n=152)	Control stent (n=155)	*P* value
TIMI flow = 3	91.4%	89.0%	0.46
TIMI flow = 2	7.9%	9.1%	0.71
TIMI flow = 0/1	0.7%	1.9%	0.62
Corrected TIMI frame count	19.5 [14.0, 24.0]	18.0 [14.0, 24.0]	0.47
IPTE*	11.2%	11.6%	0.91
RVD, mm	3.07 [2.77, 3.37]	3.05 [2.72, 3.37]	0.54
MLD, in-stent, mm	2.80 [2.54, 3.10]	2.87 [2.52, 3.12]	0.96
MLD in-lesion, mm	2.57 [2.21, 2.83]	2.53 [2.14, 2.77]	0.26
DS%, in-stent	7.7 [2.7, 12.6]	7.0 [2.4, 13.0]	0.82
DS%, in-lesion	16.1 [10.1, 24.0]	16.9 [11.1, 24.8]	0.32

*IPTE = intraprocedural thrombotic events


MASTER
MASTER II Primary Endpoint
Complete ST-segment resolution
Complete (≥70%)
Partial (>30% - <70%)
Absent (≤30%)
MGuard Prime (n=144)
Control (n=145)
10.4%
32.6%
56.9%
11.0%
29.7%
59.3%
Difference [95%CI] = -2.4% [-14.5,9.7]
P=0.68

MASTER II 30-day Clinical Events

	MGuard Prime (n=155)	Control stent (n=155)	*P* value
MACE	4 (2.6%)	7 (4.5%)	0.36
– Cardiac mortality	1 (0.6%)	3 (1.9%)	0.62
– Reinfarction	2 (1.3%)	2 (1.3%)	1.00
– TLR, ischemia-driven	4 (2.6%)	4 (2.6%)	1.00
Death, all-cause	1 (0.6%)	3 (1.9%)	0.62
TVR, ischemia-driven	4 (2.6%)	4 (2.6%)	1.00
Stent thrombosis, def/prob	4 (2.6%)	5 (3.2%)	1.00
– Definite	4 (2.6%)	4 (2.6%)	1.00
– Probable	0 (0%)	1 (0.6%)	1.00
BARC bleeding, 2-5	1 (0.5%)	2 (1.3%)	1.00

MASTER II 3-5 Day MRI Substudy

	MGuard Prime (n=28)	Control stent (n=29)	*P* value
Total LV myocardial mass, gms	129.5 [107.0, 154.5]	122.0 [112.0, 136.0]	0.57
Infarct mass, grams	31.4 [14.9, 50.5]	35.8 [16.4, 57.1]	0.45
Infarct mass (% total LV mass)	23.6 [14.2, 30.1]	29.3 [14.3, 43.0]	0.16
Total MVO, grams	0.3 [0.0, 1.8]	0.5 [0.0, 6.7]	0.39
MVO (% total LV mass)	0.2 [0.0, 1.1]	0.4 [0.0, 4.8]	0.29
Abnormal wall motion score	27 [24, 28]	26 [23, 27]	0.27
LVEF (%)	44.5 [33.8, 47.9]	43.9 [40.2, 50.1]	0.29

LV = left ventricular; EF = ejection fraction; MVO = microvascular obstruction

MASTER II
Limitations

- Single-blind
- Most control pts received DES → substantial difference between MGuard Prime and control arm in restenosis anticipated → trial terminated
- Early termination → underpowered for all endpoints

MASTER I + II Pooled Analysis

- 743 randomized pts -

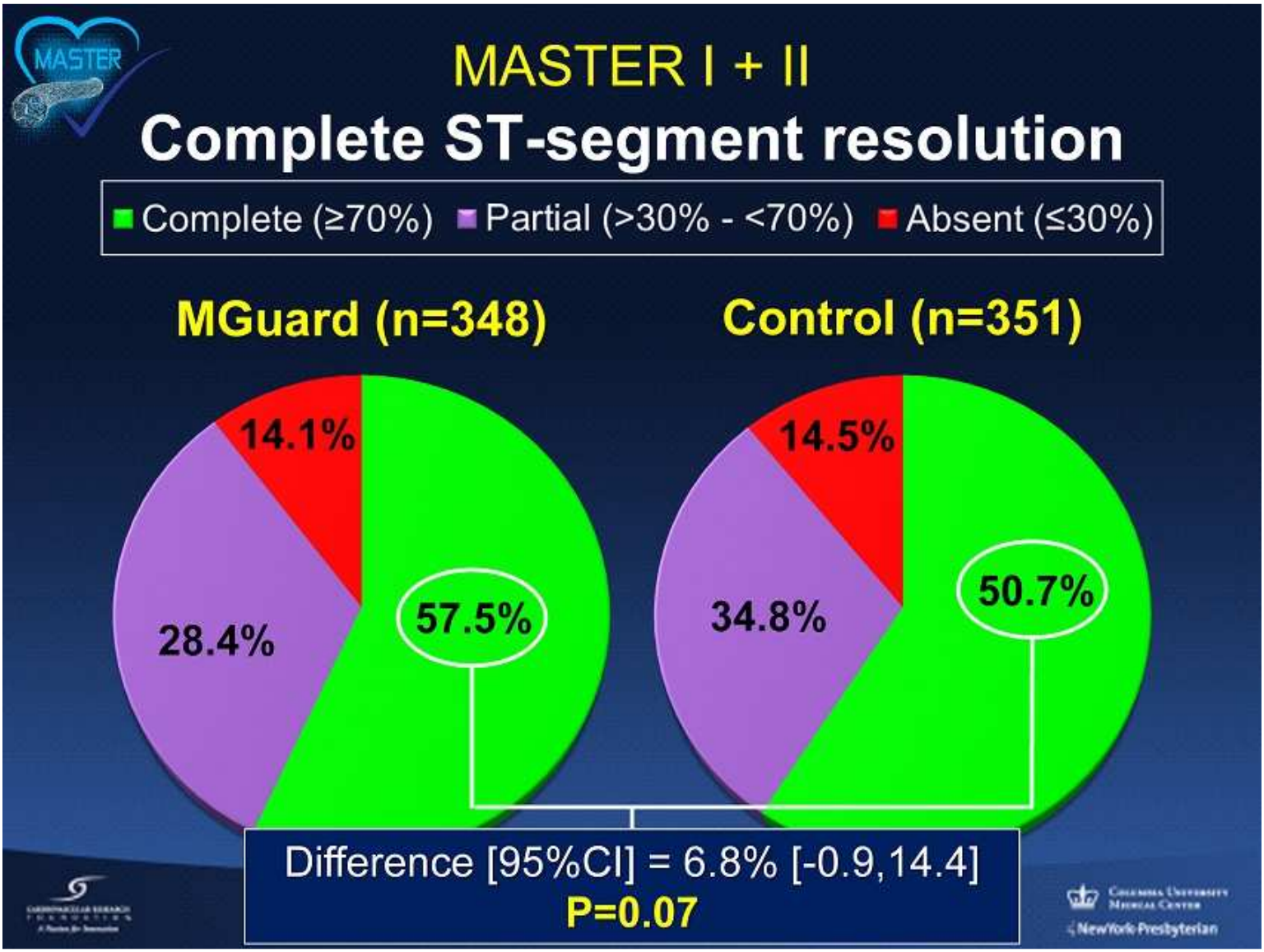
	MASTER I	MASTER II
Number of patients	433	310
- MRI substudy	59	57
Number of sites	50	46
Control arm: DES	39.8%	80.5%
MGuard arm: % Prime	12.0%	100%
Prasugrel/ticagrelor at d/c	30.1%	63.7%
Bivalirudin	11.8%	34.3%
GP IIb/IIIa inhibitor	83.1%	49.3%
Symptoms to device, mins	220 [147, 333]	171 [125, 292]
Infarct artery = LAD	40.2%	37.1%
Baseline RVD, mm	3.11 [2.87, 3.40]	3.02 [2.71, 3.33]
Baseline TIMI 0/1	70.2%	69.7%
Aspiration	66.5%	61.6%

MASTER I + II Procedural Results

	MGuard (n=372)	Control stent (n=371)	*P* value
Any device failure	5.6%	1.3%	0.03
Device success	96.2%	98.7%	0.04
Lesion success	100%	98.9%	0.62
Angiographic success	91.6%	84.9%	0.005
TIMI flow = 3	91.6%	85.4%	0.008
TIMI flow = 2	7.0%	10.5%	0.09
TIMI flow = 0/1	1.4%	4.1%	0.02
Corrected TIMI frame count	18.0 [13.0, 24.0]	18.0 [14.0, 22.0]	0.63
IPTE*	17.1%	19.7%	0.36

Device success: <50% final residual stenosis using only the randomized stent
Lesion success: <50% final residual stenosis using any percutaneous method
Angiographic success: <50% final residual stenosis and final TIMI 3 flow

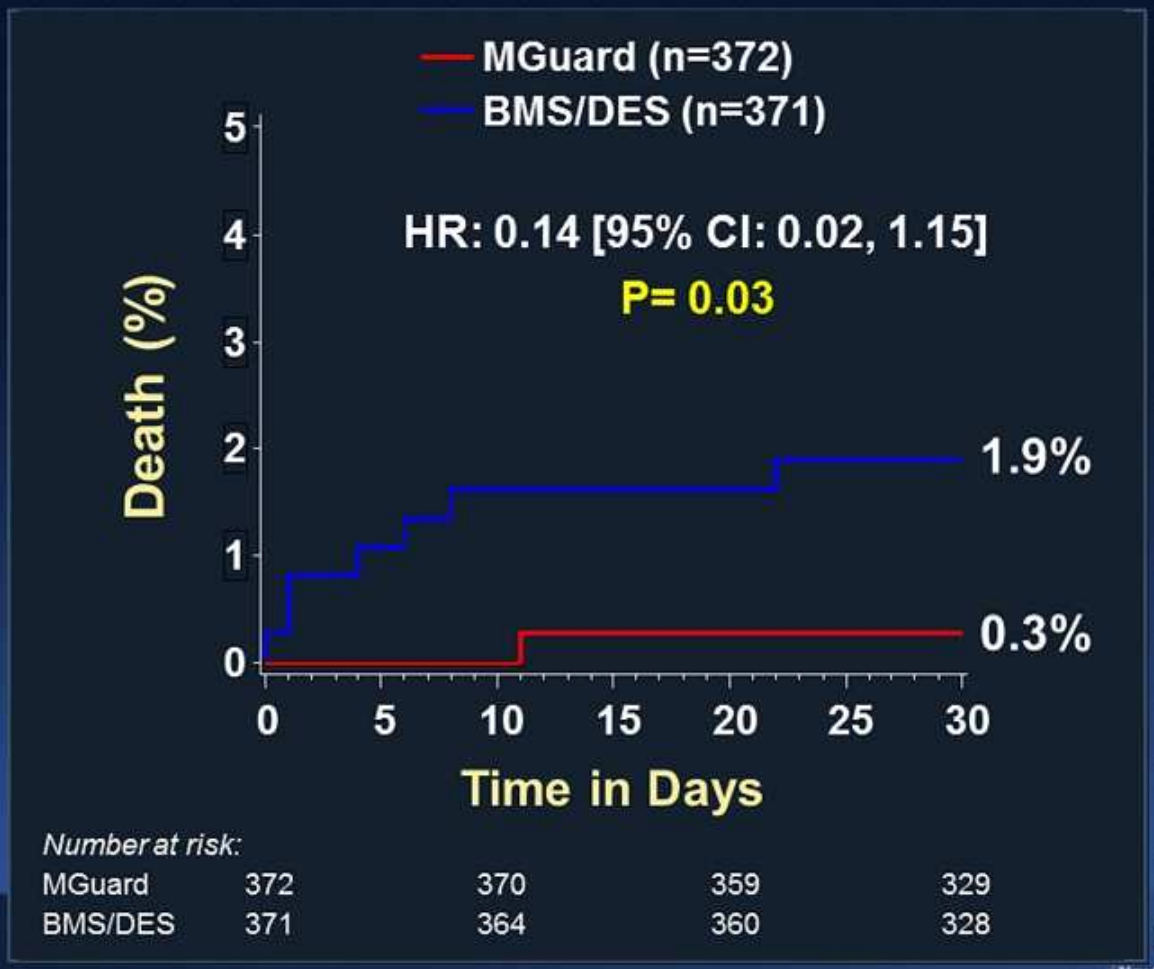
*IPTE = intraprocedural thrombotic events


MASTER
MASTER I + II
Complete ST-segment resolution
Complete (≥70%)
Partial (>30% - <70%)
Absent (≤30%)
MGuard (n=348)
Control (n=351)
14.1%
28.4%
57.5%
14.5%
34.8%
50.7%
Difference [95%CI] = 6.8% [-0.9,14.4]
P=0.07

MASTER I + II 30-day Clinical Events

	MGuard (n=372)	Control stent (n=371)	*P* value
MACE	8 (2.2%)	12 (3.2%)	0.36
– Cardiac mortality	1 (0.3%)	7 (1.9%)	0.04
– Reinfarction	5 (1.3%)	4 (1.1%)	1.00
– TLR, ischemia-driven	8 (2.2%)	5 (1.3%)	0.40
Death, all-cause	1 (0.3%)	7 (1.9%)	0.04
TVR, ischemia-driven	9 (2.4%)	5 (1.3%)	0.28
Stent thrombosis, def/prob	7 (1.9%)	7 (1.9%)	1.00
– Definite	7 (1.9%)	5 (1.3%)	0.56
– Probable	0 (0%)	2 (0.5%)	0.25
TIMI major/minor bleeding	7 (1.9%)	8 (2.2%)	0.79

MASTER I + II 30-day Mortality



Number at risk:

MGuard	372	370	359	329
BMS/DES	371	364	360	328

MASTER I + II 3-5 Day MRI Substudy

	MGuard (n=58)	Control stent (n=58)	*P* value
Total LV myocardial mass, gms	135.5 [112.0, 158.0]	130.0 [117.0, 156.0]	0.57
Infarct mass, grams	21.9 [12.5, 40.0]	29.0 [16.0, 48.7]	0.22
Infarct mass (% total LV mass)	20.5 [8.9, 28.1]	21.5 [12.0, 30.1]	0.26
Total MVO, grams	0.3 [0.0, 1.7]	1.0 [0.0, 3.8]	0.08
MVO (% total LV mass)	0.3 [0.0, 1.2]	0.8 [0.00, 2.5]	0.14
Abnormal wall motion score	26 [21, 27]	25 [21, 27]	0.83
LVEF (%)	46.9 [39.2, 50.0]	45.2 [40.9, 52.6]	0.60

LV = left ventricular; EF = ejection fraction; MVO = microvascular obstruction

MASTER II Conclusions

- The MASTER II trial was terminated prematurely due to the control arm shift in physician preference from BMS to DES, accelerating the plans to create a drug-eluting MGuard
- The significant differences in complete ST-segment resolution and TIMI-3 flow present in MASTER I with the MGuard were not apparent in MASTER II, most likely due to better outcomes in the control arm in MASTER II
- Differences in sites, patient characteristics, technique and pharmacotherapy between MASTER I and II may have contributed to these differences, as well as play of chance given the modest sample size

MASTER I and MASTER II
Conclusions

- The pooled data from 743 randomized pts in the MASTER I and MASTER II trials suggest that compared to control stents, the MGuard may be associated with improved reperfusion success and reduced 30-day mortality
- An adequately powered randomized trial is warranted to determine whether the MGuard embolic protection stent improves outcomes in pts with STEMI undergoing primary PCI

Exhibit 99.2

InspireMD Announces Important Clinical Data from MASTER and CARENET Trials

- - -

MASTER I and MASTER II Pooled Data Show Statistically Significant Mortality Benefit

CARENET 30 Day DW-MRI Data Demonstrates Significant Reduction in New Ischemic Ipsilateral Lesions

BOSTON, MA – December 15, 2014 — InspireMD, Inc . (NYSE MKT: NSPR) ("InspireMD" or the "Company"), a leader in embolic protection systems ("EPS"), today announced results from two important clinical trials. 30 day results from the MASTER II trial which enrolled 310 of a planned 1114 patients was presented at a major cardiology congress in Israel earlier today. The trial was suspended in October 2014 as a result of a corporate shift in strategy to a next generation MGuard drug eluting stent (DES) platform. The Company also announced ipsilateral DW-MRI results from the CARENET Trial for the CGuard system which successfully completed enrollment in July.

MASTER II was a global clinical trial conducted under a U.S. Food and Drug Agency (FDA) Investigational Device Exemption (IDE) and was intended for U.S. registration of the MGuard Prime coronary EPS for use in patients presenting with STEMI (**ST** -segment **E** levated **M** yocardial **I** nfarction). The MASTER II trial was designed to show superiority of ST segment resolution 60-90 minutes post procedure as well non-inferiority in all-cause death or recurrent target vessel myocardial infarction. While the trial was halted well short of the planned enrollment, the Company elected to unblind the data and present the results on behalf of the study investigators.

Today at the International Conference for Innovations in Cardiovascular Systems meeting in Tel Aviv Israel, Dr. Gregg Stone, Professor of Medicine at Columbia University and principal investigator of the trial, presented 30 day results on the 310 patients enrolled in MASTER II as well as pooled data from MASTER II and the 433 patient MASTER I trial completed and published in 2012. While in MASTER I, the primary endpoint of superiority in ST-segment resolution was achieved (57.8% vs. 44.7%, p=0.008), MASTER II did not show a difference in ST-segment resolution between MGuard and control stents (FDA-approved bare metal or drug eluting stents) 56.9% vs. 59.3% (p=0.68). Pooled data between MASTER I and MASTER II for ST resolution continued to favor MGuard 57.5% vs. 50.7% for control (p=0.07).

Impressively, 30 day mortality results for the MGuard in the MASTER II trial remained low (0.6% vs. 1.9%, p=0.62), consistent with all previous MGuard trials and registries and overall MACE (Major Adverse Cardiac Events) was favorable for MGuard (2.6% vs. 4.5% p=0.36). Pooled mortality data for MASTER I and II showed a statistically significant reduction in mortality with MGuard (0.3% vs. 1.9%, p=0.04). Infarct size, another important indicator of mortality, showed a positive trend for MGuard in MASTER II (mean 22.60% vs. 27.48%, p=0.16), as well as in the pooled analysis (mean 18.80% vs. 22.24%, p=0.26).

"The data from MASTER II supports further clinical evaluation of the MGuard Prime EPS," stated Dr. Stone. "While the number of patients enrolled in MASTER II were not powered for any endpoints, it was encouraging to see the significant difference in mortality with the pooled data, with other indicators of improved reperfusion success with the MGuard technology. We look forward to the development of a DES version of MGuard in the near future to continue a pivotal clinical evaluation of the MicroNet embolic protection system."

CARENET data was also presented today at the ICI in Tel Aviv by Prof. Piotr Musiałek, Co-Principal Investigator for the CARENET study, from Jagiellonian University Medical College at John Paul II Hospital, in Krakow, Poland. He reported new positive clinical data from the CGuard ™ CARENET (**CAR** otid **E** mbolic protection study using micro **NET**) Trial. The CARENET trial recruited a total of 30 patients and showed exceptional safety and efficacy with 0% MACCE (meaning no death, stroke or myocardial infarction) at 30 days, substantially lower than in other carotid stenting trials. Additionally, the incidence of new ischemic ipsilateral lesions as assessed by Diffusion Weighted Magnetic Resonance Imaging (DW-MRI) after carotid artery stenting was 37.0%, a reduction of approximately 50% when compared to published historical control groups of non-mesh covered carotid stents.The CARENET trial also reported an average lesion volume per patient that was 10 times smaller than historical control groups. The reduction in both the incidence and volume of new ischemic lesions indicates therapeutic benefits of the MicroNet technology and that the benefits of using this device may extend beyond the acute procedural period.

Alan Milinazzo, CEO of InspireMD commented, “We are very encouraged to see the trend in mortality improvement with MGuard in MASTER II and very excited to show a statistically significant benefit in mortality when our two MASTER randomized trials are pooled together. These data further support our strategy in partnering with a drug eluting stent manufacturer to re-enter the clinic to conduct a pivotal trial that will not only enroll more quickly but may ultimately show the definitive benefit of the MicroNet embolic protection in patients presenting with STEMI.” Milinazzo added, “Our CGuard product continues to excite physicians during our limited market release (LMR) and today’s positive CARENET data should generate even more interest in using this breakthrough technology.”

“ **About Stenting and MGuard™ Prime EPS**

Standard stents were not engineered for heart attack patients. They were designed for treating stable angina patients whose occlusion is different from that of an occlusion in a heart attack patient.
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 Prime EPS is integrated with a precisely engineered micro net mesh that is 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 mortality based on our MASTER I and MASTER II data, the MGuard Prime EPS requires no change in current physician practice – an important factor in promoting acceptance and general use in time-critical emergency settings.

About CGuard EPS

The proprietary CGuard EPS uses the same MicroNet technology featured on the MGuard™ and MGuard Prime™ coronary embolic protection systems. The MicroNet technology is a single fiber knitted mesh wrapped on an open cell stent platform designed to trap debris that can dislodge and travel downstream after a patient is treated with traditional stenting methods. This technology seeks to protect patients from plaque debris and blood clots breaking off and which can lead to life threatening strokes. The size, or aperture, of the MicroNet ‘pore’ is only 150-180 microns in order to maximize protection against the potentially dangerous plaque and thrombus within the carotid artery.

MGuard EPS and CGuard EPS are CE Mark approved. MGuard EPS and CGuard EPS, however, are not approved for sales in the U.S. by the U.S. Food and Drug Administration at this time.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MGuard™ with MicroNet ™ technology to make its products the industry standard for embolic protection and to provide a superior solution to the key clinical issues of current stenting in patients with a high risk of distal embolization, no reflow and major adverse cardiac events.

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

Forward-looking Statements

This press release contains "forward-looking statements." Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" 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 (i) market acceptance of our existing and new products, (ii) negative clinical trial results or lengthy product delays in key markets, (iii) an inability to secure regulatory approvals for the sale of our products, (iv) intense competition in the medical device industry from much larger, multinational companies, (v) product liability claims, (vi) product malfunctions, (vii) our limited manufacturing capabilities and reliance on subcontractors for assistance, (viii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (ix) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (x) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (xi) our reliance on single suppliers for certain product components, (xii) the fact that we will need to raise additional capital to meet our business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain and (xiii) 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. 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 Transition Report on Form 10-KT 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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