12 month results from the MDT-2113 SFA Japan trial - DCB vs. standard PTA for the treatment of atherosclerotic lesions in the SFA/PPA

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on behalf of the MDT-2113 SFA Japan Investigators

Disclosure

Speaker name: Hiroyoshi Yokoi, MD

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I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☒ I do not have any potential conflict of interest

MDT-2113 SFA Japan Trial Overview

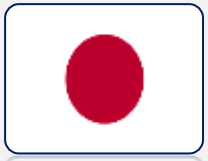
<u>Objective</u>: Assess the safety and efficacy of MDT-2113 (IN.PACT Admiral) DCB for the interventional treatment of *de novo* and non-stented restenotic lesions in the superficial femoral artery and the proximal popliteal artery as compared to treatment with standard percutaneous transluminal angioplasty

- Prospective, multi-center, randomized (2:1), single blinded trial
- 100 subjects enrolled at 11 sites in Japan
  - MDT-2113 DCB (n=68) vs. PTA (n=32)
- Independent and blinded Duplex Ultrasound Core Lab,[1] Angiographic Core Lab,[2] and Clinical Events Committee[3]
- External Monitoring, 100% Source Data Verification

1. VasCore DUS Core Laboratory, Boston, MA, US;
2. SynvaCor Angiographic Core Laboratory, Springfield, IL, US;
3. Clinical Events Committee and Data Safety Monitoring services provided by HCRI, Boston, MA, US

MDT-2113 SFA Japan Trial

Investigators and Sites



MDT-2113 SFA Japan

100 subjects enrolled at 11 sites in Japan

Shigeru Saito, MD	Shonan Kamakura General Hospital	Kamakura, Kanagawa, Japan
Masato Nakamura, MD	Toho University Medical Center, Ohashi Hospital	Meguro-Ku, Tokyo, Japan
Keisuke Hirano, MD	Yokohama Tobu Hospital	Tsurumi-Ku, Yokohama, Kan, Japan
Osamu Iida, MD	Kansai Rosai Hospital	Amagasaki, Hyogo, Japan
Kazushi Urasawa, MD	Tokeidai Memorial Hospital	Sapporo, Hokkaido, Japan
Naoto Inoue, MD	Sendai Kousei Hospital	Sendai, Miyagi, Japan
Hiroshi Ando, MD	Kasukabe Chuo General Hospital	Kasukabe, Saitama, Japan
Junko Hone, MD	Kikuna Memorial Hospital	Yokohama, Kanagawa, Japan
Takuo Nakagami, MD	Omihachiman Community Medical Center	Omihachiman, Siga, Japan
Hiroyoshi Yokoi, MD	Fukuoka Sanno Hospital	Fukuoka, Fukuoka, Japan
Kenji Ando, MD	Kokura Memorial Hospital	Kitakyushu, Fukuoka, Japan

MDT-2113 SFA Japan Trial
Primary Endpoints

– **Primary Effectiveness Endpoint:** Primary patency at 12 months, defined as freedom from clinically-driven target lesion revascularization and freedom from restenosis as determined by duplex ultrasound-derived PSVR ≤ 2.4

– **Primary Safety Endpoint:** Freedom from device- and procedure-related death through 30 days, and freedom from target limb major amputation and clinically-driven target vessel revascularization within 12 months post index procedure

MDT-2113 SFA Japan Trial
Key Eligibility Criteria

• Key Inclusions

- RCC 2, 3 and 4
- Lesion in SFA and/or PPA
- Single *de novo* or non-stented restenotic lesion:
  - 70-99% occluded with total length ≥4 cm and ≤ 20 cm
  - 100% occluded total length ≤ 10 cm
  - Combination and tandem lesions allowed if criteria above met and lesion gap ≤ 3 cm
- Evidence of adequate distal run-off through the foot

• Key Exclusions

- RCC 5 and 6
- Stroke or STEMI ≤ 3 months prior to enrollment
- Chronic renal insufficiency
- Contralateral SFA/PPA disease requiring treatment at index procedure
- Any major surgical procedure or intervention performed or planned ≤ 30 days of index
- Unsuccessful lesion crossing

MDT-2113 SFA Japan Trial
Baseline Clinical Characteristics

Subject Characteristics	MDT-2113 DCB	PTA	p-value
Age, Y ± SD	73.3 ± 7.4 (68)	74.2 ± 6.1 (32)	0.539
Male Gender (%)	73.5% (50/68)	81.3% (26/32)	0.461
Obesity (BMI ≥ 30 kg/m^2) (%)	4.4% (3/68)	0.0% (0/32)	0.549
Diabetes Mellitus (%)	58.8% (40/68)	56.3% (18/32)	0.831
Insulin Dependent Diabetes Mellitus (%)	14.7% (10/68)	18.8% (6/32)	0.771
Current Smoker (%)	26.5% (18/68)	31.3% (10/32)	0.639
Carotid Artery Disease (%)	18.5% (12/65)	16.1% (5/31)	1.000
Coronary Heart Disease (%)	50.0% (34/68)	50.0% (16/32)	1.000
Renal Insufficiency (%)	8.8% (6/68)	12.5% (4/32)	0.722
Rutherford Category (%) 2	54.4% (37/68)	59.4% (19/32)	
3	41.2% (28/68)	37.5% (12/32)	0.623
4	4.4% (3/68)	3.1% (1/32)	
ABI	0.764 ± 0.145 (68)	0.735 ± 0.166 (32)	0.384

MDT-2113 SFA Japan Trial

Baseline Lesion Characteristics

Subject Characteristics	MDT-2113 DCB n=68	PTA n=32	p-value
Lesion Type [1] De novo	91.2% (62/68)	100.0% (32/32)	0.085
Restenotic (non-stented)	8.8% (6/68)	0.0% (0/32)	
Prox. Popliteal Involvement	1.5% (1/68)	3.1% (1/32)	0.540
Lesion length (cm ± SD) [2]	9.15 ± 5.85 (68)	8.89 ± 6.01 (32)	0.838
Total occlusions, % (n)	16.2% (11/68)	15.6% (5/32)	1.000
Severe calcification, % (n)	7.4% (5/68)	9.4% (3/32)	0.708
Reference Vessel Diameter (mm)	4.843 ± 0.751 (68)	4.675 ± 0.661 (32)	0.280
Mean Lesion Diameter pre (mm)	0.971 ± 0.731 (68)	0.896 ± 0.594 (32)	0.610
Diameter Stenosis (%)	80.2 ± 14.1 (68)	80.7 ± 12.5 (32)	0.861

1. Site-reported
2. Normal-to-normal by Core Lab QVA evaluation

MDT-2113 SFA Japan Trial
Procedural Characteristics

Procedural Characteristics		MDT-2113 DCB (n=68 Subjects)	PTA (n=32 Subjects)	p-value
Pre-Dilatation (%) [1]		100.0% (68/68)	100.0% (32/32)	> 0.999
Post-dilatation (%) [1]		23.5% (16/68)	18.8% (6/32)	0.796
Index Procedural IVUS Use (%) [1]		39.7% (27/68)	25.0% (8/32)	0.181
Dissections (%)	0	26.5% (18/68)	28.1% (9/32)	
	A-C	73.5% (50/68)	71.9% (23/32)	0.235
	D-F	0.0% (0/68)	0.0% (0/32)	
Provisional Stenting (%) [1]		4.4% (3/68)	3.1% (1/32)	0.759
Device Success (%) [2]		100.0% (97/97)	97.1% (33/34)	0.260
Procedural Success (%) [3]		97.1% (66/68)	100.0% (32/32)	>0.999
Clinical Success (%) [4]		97.1% (66/68)	100.0% (32/32)	>0.999

1. Site-reported
2. Device success: Successful delivery, inflation, deflation and retrieval of the intact study balloon without burst < RBP
3. Procedural success: Residual stenosis ≤ 50% for non-stented subjects or ≤ 30% for stented subjects
4. Clinical success: Procedural success without procedural complications (death, major target limb amputation, thrombosis of target lesion or TVR) prior to discharge

MDT-2113 SFA Japan Trial

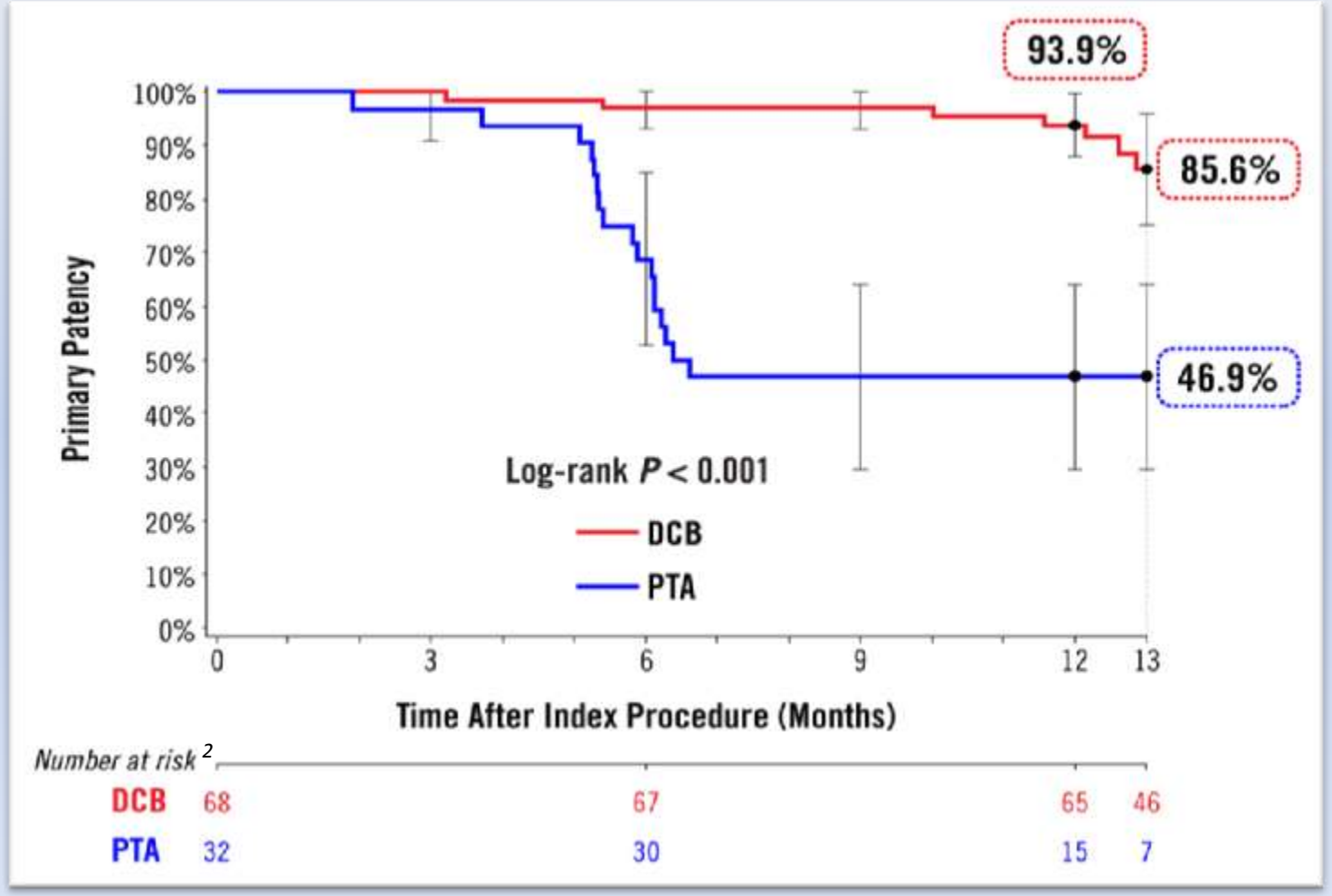
12-Month Primary Outcomes- Per Protocol, All ITT

	MDT-2113 DCB	PTA	Difference [95%CI]	p-value
Primary Effectiveness Primary Patency [1]	89.2% (58/65)	48.4% (15/31)	38.2% [19.2%, 57.3%]	< 0.001[4]

	MDT-2113 DCB	PTA	Difference [97.5%CI][3] Difference [95%CI]	p-value
Primary Safety Composite[2]	95.6% (65/68)	81.3% (26/32)	14.3% [1.8%, 31.1%]	0.028[4]

1. Primary Patency is defined as freedom from clinically-driven TLR and freedom from restenosis as determined by duplex ultrasound (DUS) Peak Systolic Velocity Ratio (PSVR) ≤ 2.4
2. Primary safety composite is defined as freedom from device and procedure-related 30-day death and freedom from target limb major amputation and clinically-driven TVR through 12 months
3. Non-inferiority margin -10%
4. Superiority test p-value

MDT-2113 SFA Japan Trial
Primary Patency[1] at 12 Months



1. Freedom from core laboratory-assessed restenosis (duplex ultrasound PSVR ≤2.4) and clinically-driven target lesion revascularization through 12 months (adjudicated by a Clinical Events Committee blinded to the assigned treatment)
2. Number at risk represents the number of evaluable subjects at the beginning of the 30-day window prior to each follow-up interval

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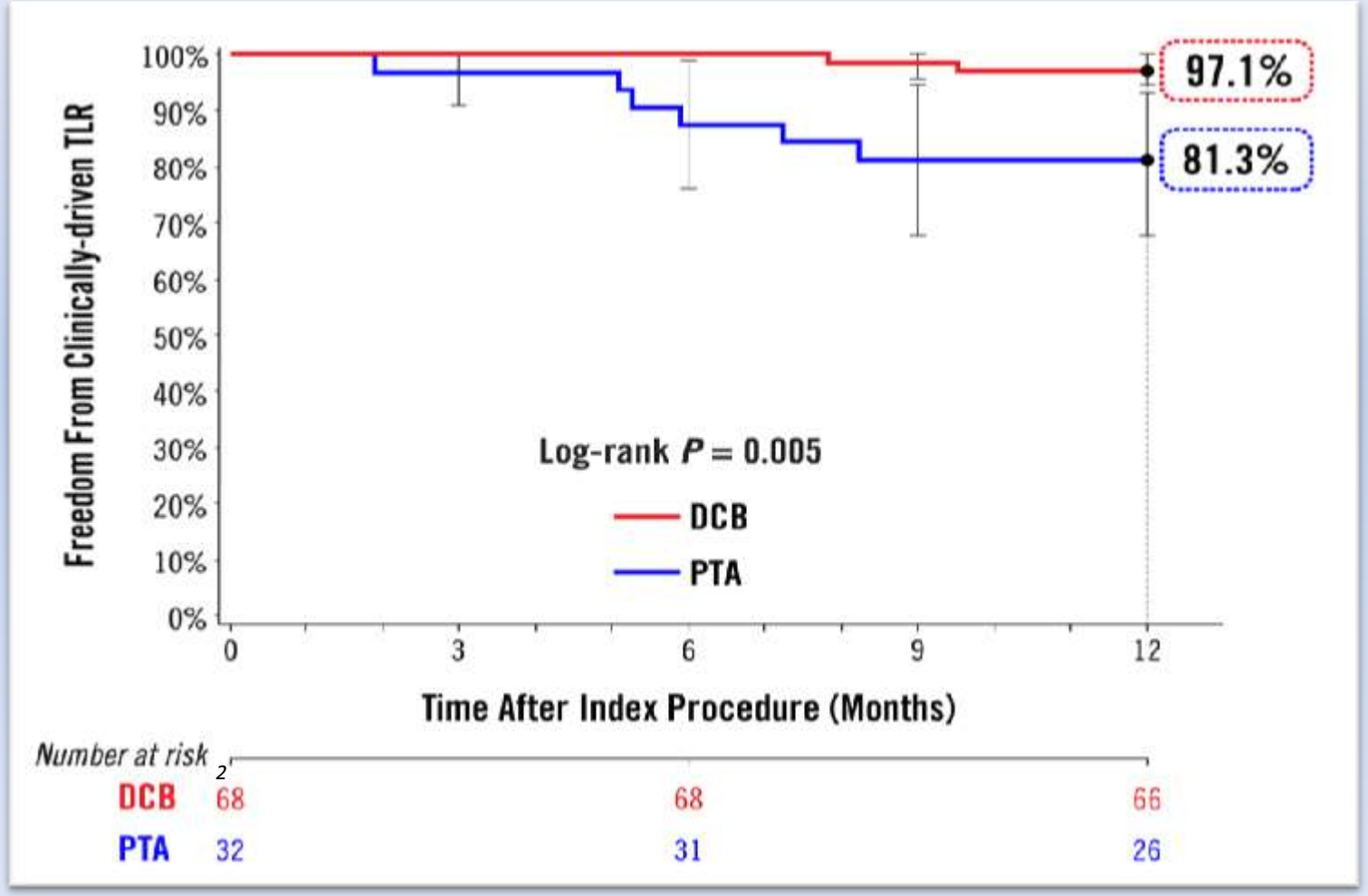
Freedom from CD-TLR at 12 Months



1. Number at risk represents the number of evaluable subjects at the beginning of the 30-day window prior to each follow-up interval

MDT-2113 SFA Japan Trial
Effectiveness Outcomes at 12 Months

	MDT-2113 DCB	PTA	p-value
Clinically-driven TLR [1]	**2.9% (2/68)**	**18.8% (6/32)**	**0.012**
All TLR [2]	2.9% (2/68)	18.8% (6/32)	0.012
Primary Sustained Clinical Improvement [3]	93.8% (61/65)	71.0% (22/31)	0.004
ABI	0.933 ± 0.122 (68)	0.923 ± 0.143 (32)	0.722

1. Clinically-driven TLR is defined as any re-intervention within the target vessel due to symptoms or drop of ABI/TBI of ≥20% or >0.15 when compared to post-procedure baseline ABI/TBI.
2. All TLR includes clinically-driven and incidental or duplex-driven TLR
3. Freedom from target limb amputation, TVR, and increase in Rutherford class at 12 months post-procedure

MDT-2113 SFA Japan Trial
Safety Outcomes at 12 Months

	MDT-2113 DCB	PTA	p-value
Primary Safety Composite[1]	95.6% (65/68)	81.3% (26/32)	0.028
30-day Device- & Proc.-related Death	0.0% (0/68)	0.0% (0/32)	> 0.999
12-month Clinically Driven TVR	4.4% (3/68)	18.8% (6/32)	0.028
12-month Target Limb Major Amputation	0.0% (0/68)	0.0% (0/32)	> 0.999
12-month Major Adverse Event[2]	4.4% (3/68)	18.8% (6/32)	0.028
All-cause Death	0.0% (0/68)	0.0% (0/32)	> 0.999
Thrombosis	0.0% (0/68)	0.0% (0/32)	> 0.999

1. Primary safety composite is defined as freedom from device- and procedure-related 30-day death and freedom from target limb major amputation and clinically-driven TVR through 12 months
2. MAE is defined as composite of death, clinically-driven TVR, target limb major amputation, and thrombosis within 12 months

MDT-2113 SFA Japan Trial
Summary

Results demonstrate superior treatment effect of MDT-2113 (IN.PACT Admiral) DCB over PTA at 12-months

- First reported outcomes from an independently-adjudicated, randomized, single blind trial evaluating DCB in Japanese patients
- Results show superiority of MDT-2113 DCB over PTA

	MDT-2113 DCB	PTA	p-value
Primary Patency	**93.9%**	46.9%	<0.001
CD-TLR	**2.9%**	18.8%	0.012

- Data are consistent with superior treatment outcomes seen in other IN.PACT SFA DCB trials

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