Twelve Month Results From the IN.PACT DCB in a Chinese Population

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Presented on behalf of the IN.PACT China SFA Investigators

Disclosures

Speaker name:

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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)

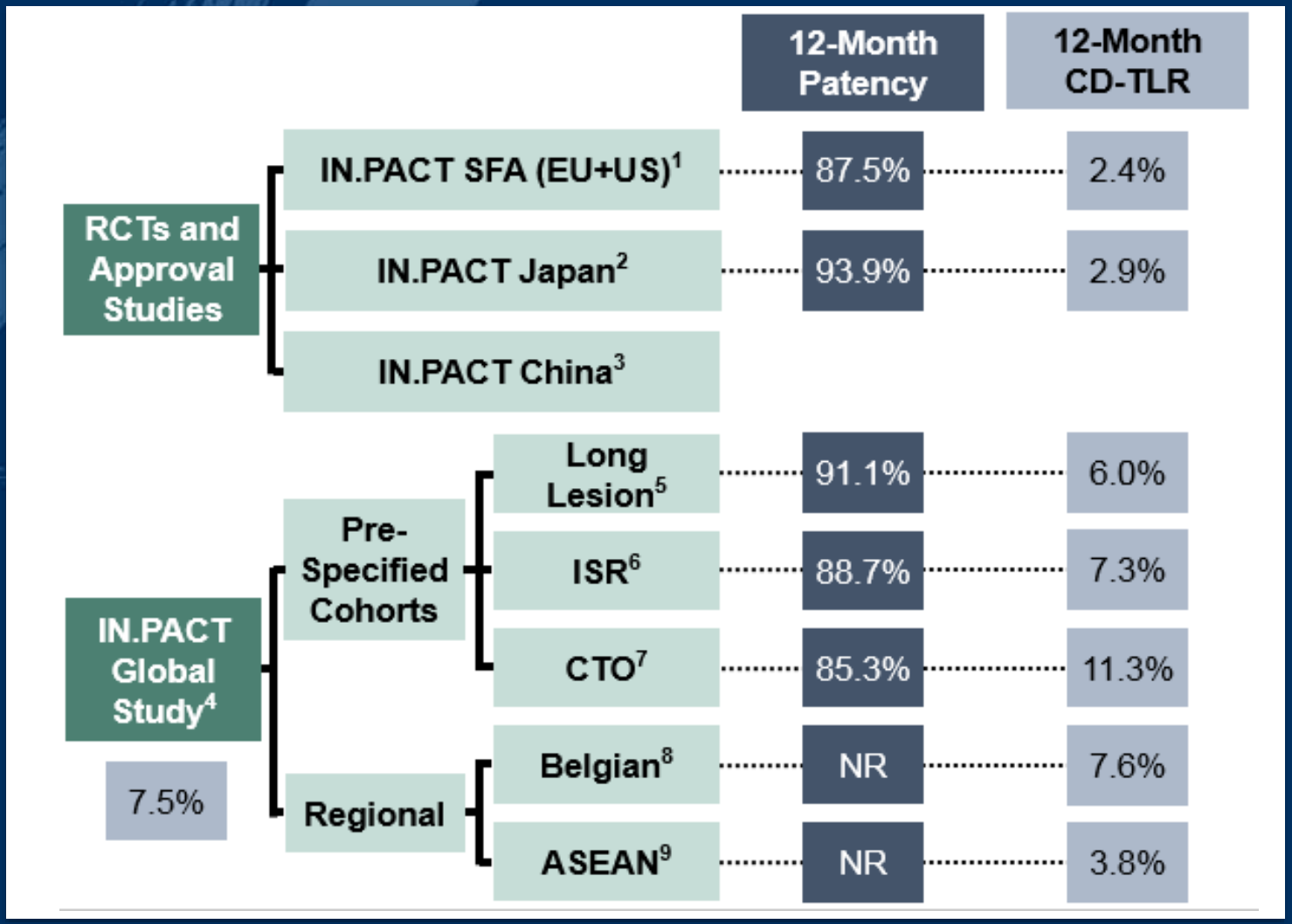
- ☒ I do not have any potential conflict of interest

Background

- Drug-coated balloons have shown improved patency results over PTA in randomized trials[1-7]
- IN.PACT Admiral is the only DCB to show long term benefits through 4 years in the IN.PACT SFA trial and 2 years in the IN.PACT Global study[1-4, 8, 9]
- Performance of DCBs in several populations is still poorly understood

1. Tepe G. et al., Circulation. 2015.
2. Laird et al., J Am Coll Cardiol. 2015.
3. Krishnan, P. IN.PACT SFA 3 Year Results, VIVA 2016.
4. Schneider, P. IN.PACT SFA 4 Year Results, VIVA 2017.
5. Rosenfield et al., N Engl J Med. 2015.
6. Krishnan, P. et al., Circulation. 2017
7. Schroeder, H. et al., Circulation. 2017.
8. Jaff, M. IN.PACT Global 1 Year Results, VIVA 2016.
9. Zeller, T. IN.PACT Global 2 Year Results, VIVA 2017.

IN.PACT DCB Clinical Program



1. Tepe G. et al., Circulation 2015; Medtronic IFU Rev 1F.
2. Iida, O. LINC 2017
3. Chen, Z. VEITH 2017.
4. Jaff, M. VIVA 2016.
5. Scheinert, D. EuroPCR 2015.
6. Brodmann, M. VIVA 2015.
7. Tepe, G. Charing Cross 2016.
8. DeLoose, K. LINC 2017.
9. Choi, D. LINC 2017.

IN.PACT SFA China Study

- Prospective
- Multi-center (15 sites)
- Single Arm

- Rigorous
  - Independent core labs [1, 2]
  - Clinical Events Committee [3]

Study Population
Chinese patients (n=143) with *de novo* and non-stented restenotic lesions in the SFA/PPA
RCC 2-4

Treatment
IN.PACT Admiral DEB*

Follow-up	30 D	6 M	12 M
			
	± 7D	**± 30D**	**± 30D**

1. VasCore DUS Core Laboratory, Boston, MA, US
2. Beth Israel Deaconess Medical Center, Boston, MA, US
3. Clinical Event Committee and Data Safety Monitoring provided by Syntactx, NY, US

* After completion of the clinical trial the study product name has been updated to IN.PACT Admiral Paclitaxel coated PTA balloon catheter which is also referred to as theIN.PACT Admiral DCB. The generic name of the product used is Drug Coated Peripheral Balloon Dilating Catheter.

IN.PACT SFA China Study
Endpoints

- **Primary Efficacy Endpoints:** Primary Patency within **12 months**[1]

- **Primary Safety Endpoint: 30-day** Safety Composite[2]

Both endpoints were powered and compared to a Performance Goal derived from the literature

1. Defined as freedom from clinically-driven TLR and freedom from restenosis as as determined by DUS and PSVR ≤ 2.4 within 12 months post-index procedure.
2. Defined as composite of freedom from device- and procedure-related mortality, freedom from major target limb amputation and freedom from clinically-driven TLR within 30 days post-index procedure.

IN.PACT SFA China

Select Baseline and Procedural Characteristics

Patient Characteristics	N=143 Subjects
Age, Y ± SD	66.8 ± 7.7
Male Gender (%)	74.8% (107/143)
Diabetes Mellitus (%)	46.2% (66/143)
Current Smoker (%)	36.4% (52/143)

Lesion Characteristics	N=143 Subjects N=143 Lesions
Lesion Type [1] De novo Restenotic (non-stented)	 99.3% (142/143) 0.7 % (1/143)
Lesion length (cm ± SD) [2]	10.40 ± 6.51
Total occlusions, % (n) [2]	52.4% (75/143)
Severe calcification, % (n) [2]	11.9% (17/143)

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

Procedural Characteristics		N=143 Subjects N=143 Lesions
Pre-Dilatation (%) [1]		100% (143/143)
Post-dilatation (%) [1]		14.0% (20/143)
Dissections (%)	0	18.9% (27/143)
	A	0.0% (0/143)
	B-C	55.3% (79/143)
	D	25.9% (37/143)
	E-F	0.0% (0/143)
Provisional Stenting (%) [1]		4.2% (6/143)
Device Success (%) [3]		97.6% (206/211)
Procedural Success (%) [4]		91.5% (130/142)
Clinical Success (%) [5]		89.4% (127/142)

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

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	DEB	95%CI	Performance Goal	p-value
Primary Efficacy Primary Patency [1]	**88.6% (109/123)**	[81.6%, 93.6%]	50%	< 0.001

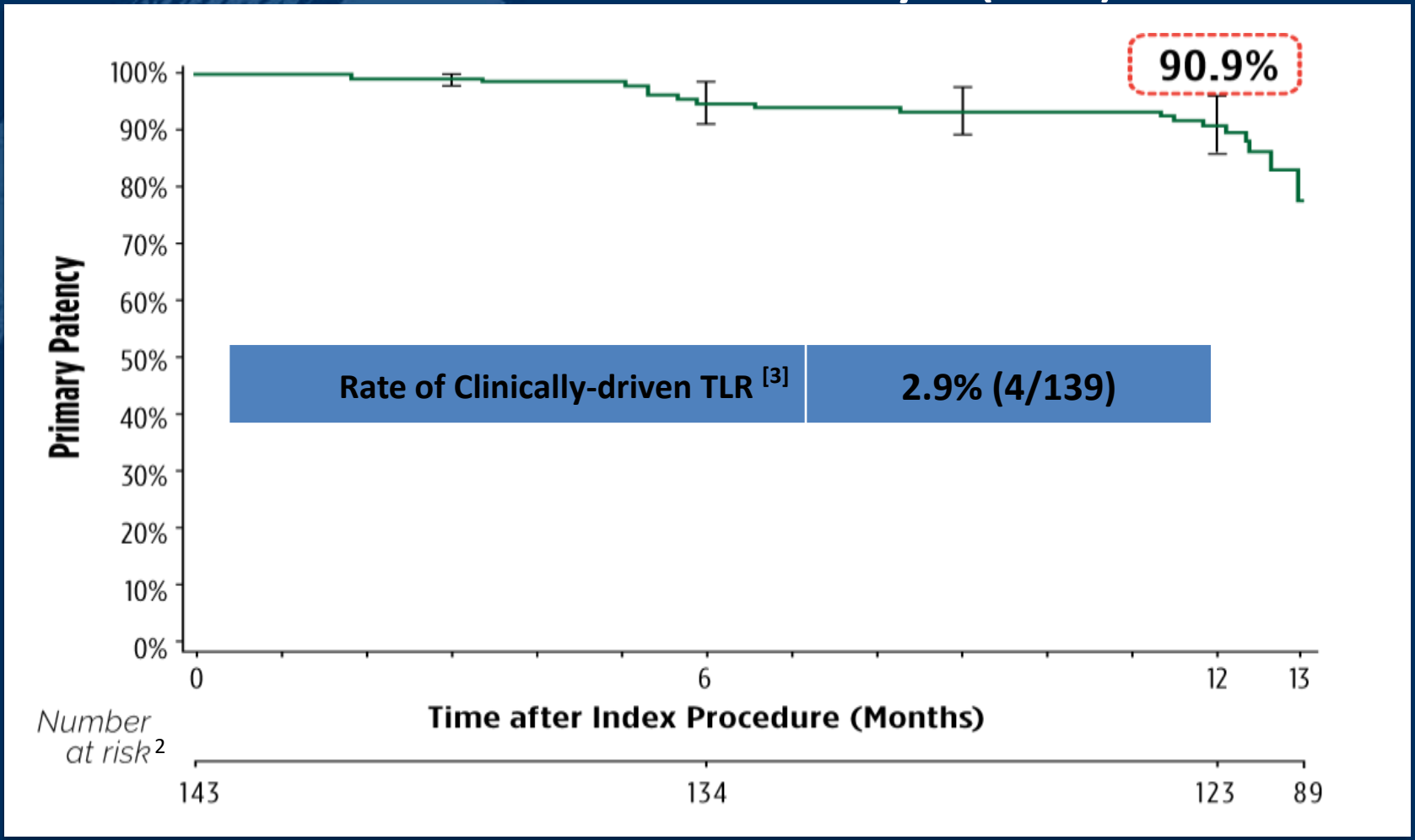
	DEB	95%CI	Performance Goal	p-value
Primary Safety Composite [2]	**99.3% (141/142)**	[96.1%, 100.0%]	88%	< 0.001

Primary endpoints met

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 in ITT non-stented subjects.
2. Primary safety composite is defined as freedom from device- and/or procedure-related mortality, freedom from major target limb amputation and freedom from clinically-driven TLR within 30 days post-index procedure in ITT subjects.

IN.PACT SFA China Study

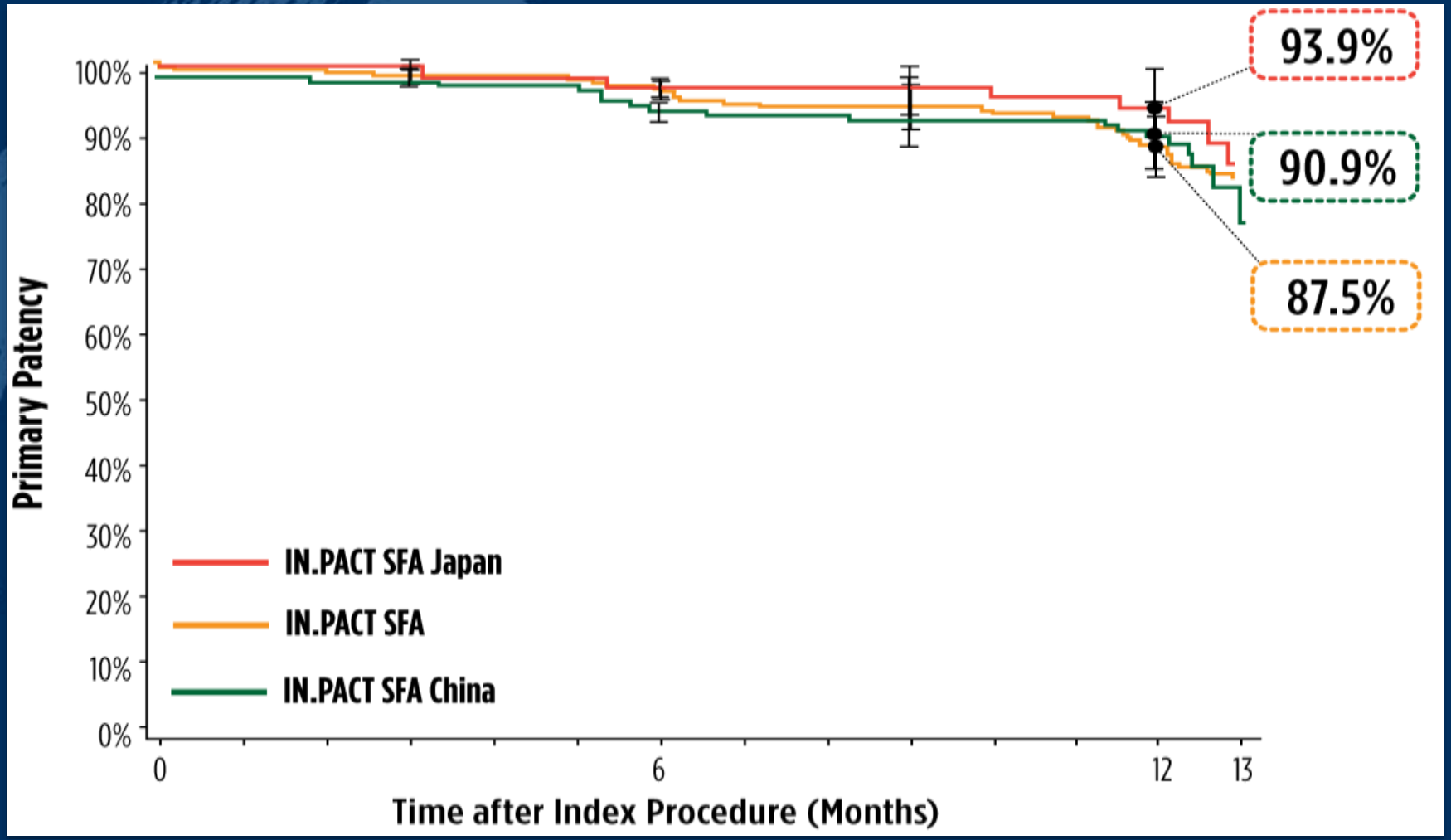
12-Month Patency[1] (ITT)



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)
2. Number at risk represents the number of evaluable subjects at the beginning of the 30-day window prior to each follow-up interval
3. Clinically-driven TLR is defined as any re-intervention at the target lesion due to symptoms or drop of ABI/TBI of ≥20% or >0.15 when compared to post-procedure baseline ABI/TBI.

IN.PACT SFA China Study

Consistent Patencies Across IN.PACT Studies



1. Tepe G. et al., IN.PACT SFA 12 Month Results. Circulation 2015; Medtronic IFU Rev 1F.
2. Iida, O. IN.PACT Japan 12 Month Results. LINC 2017
3. Chen, Z. VEITH 2017.

12-Month Outcomes - IN.PACT Trials

	IN.PACT SFA China[1]	IN.PACT SFA[2]	IN.PACT Global[3]	IN.PACT Global ASEAN[4]	IN.PACT Japan[5]	AcoArt I (Acotec)[6]
	n=143	n=220	n=1406	n=114	n=68	n=100
Lesion Length (Mean ± SD, cm)	10.4 ± 6.5	8.9 ±4.5	12.1 ± 9.5	17.4 ± 12.3	9.2 ± 5.9	14.7 ± 10.9
Provisional Stenting	4.2%	7.3%	25.3%	19.3%	4.4%	19.0%
Primary Patency (KM @ 360 days)	90.9%	87.5%	NA	NA	93.9%	76.1%
CD-TLR	**2.9%**	**2.4%**	**7.5%**	**3.8%**	**2.9%**	**6.1%**
Any TLR	3.6%	2.9%	7.8%	3.8%	2.9%	7.2%
Mortality	2.9%	1.9%	3.5%	8.5%	0.0%	2.0%
Major Target Limb Amputation	0.0%	0.0%	0.2%	0.0%	0.0%	0.0%
Thrombosis	2.2%	1.4%	2.9%	0.9%	0.0%	NA

1. Chen, Z. VEITH 2017.
2. Tepe et al., Circulation 2015; Medtronic Data on File
3. Jaff, M. VIVA 2016.
4. Choi, D. LINC 2017.
5. Iida, O. LINC 2017.
6. Jia et al., JACC Cardiovasc Interv. 2016.

12-Month Outcomes - IN.PACT Trials

	IN.PACT SFA China[1]	IN.PACT SFA[2]	IN.PACT Global[3]	IN.PACT Global ASEAN[4]	IN.PACT Japan[5]	AcoArt I (Acotec)[6]
	n=143	n=220	n=1406	n=114	n=68	n=100
Lesion Length (Mean ± SD, cm)	10.4 ± 6.5					
Provisional Stenting	4.2%					
Primary Patency (KM @ 360 days)	90.9%					
CD-TLR	**2.9%**					
Any TLR	3.6%					
Mortality	2.9%					
Major Target Limb Amputation	0.0%					
Thrombosis	2.2%	1.4%	2.9%	0.9%	0.0%	NA

IN.PACT SFA China Study

Independent Duplex Ultrasound Core Lab [1]

Angiographic Core Lab [2]

Clinical Event Committee [3]

External Monitoring, 100% Source Data Verification

1.VasCore DUS Core Laboratory, Boston, MA, US

2.Beth Israel Deaconess Medical Center, Boston, MA, US

3.Clinical Event Committee and Data Safety Monitoring provided by Syntactx, NY, US

1. Chen, Z. VEITH 2017.
2. Tepe et al., Circulation 2015; Medtronic Data on File
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IN.PACT SFA China Study
Summary

Results demonstrate remarkable performance of the IN.PACT Admiral DEB in a Chinese population at 12 months

- By Kaplan-Meier estimate, primary patency at 12 months was **90.9%**
- Results show a low CD-TLR rate of **2.9%** at 12-months
- Study met predefined safety and efficacy objectives
- These data are consistent with outcomes reported from other IN.PACT Trials, showing strong performance of IN.PACT Admiral DCB/DEB

Thank you!

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