IN.PACT DCB Clinical Program Update

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Disclosure Statement

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below

- Grant/Research Support: Medtronic, B Braun, Boston Scientific, Leipzig University, Biotronik
- Consulting Fees/Honoraria: Medtronic, Boston Scientific, Biotronik, B Braun
- Major Stock Shareholder/Equity: N/A

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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

IN.PACT DCB Clinical Program

Safety and Efficacy of the IN.PACT Admiral DEB in a Chinese Population: 12-Month Results of the IN.PACT SFA China Study

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Presented on behalf of the IN.PACT China SFA Investigators

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- No disclosures
1. VasCore DUS Core Laboratory, Boston, MA, US
2. Site-reported
3. Defined as composite of freedom from device- and procedure-related mortality, freedom from major target limb amputation and de-novo and non stented restenotic lesions
4. Defined as freedom from clinically-driven TLR and freedom from restenosis as determined by duplex ultrasound PSVR ≤2.4 within 12 months post-index procedure.
5. Defined as freedom from device- and/or procedure-related mortality, freedom from major target limb amputation and de-novo and non stented restenotic lesions
6. In-stent restenosis (ITSR) was defined as duplex ultrasound PSVR > 2.4 within 12 months post-index procedure.
7. Normal-to-normal by Core Lab QVA evaluation
8. Clinical events committee and Data Safety Monitoring provided by Syntactx, NY, US
9. See the literature
10. Defined as composite of freedom from device- and procedure-related mortality, freedom from major target limb amputation and de-novo and non stented restenotic lesions
11. Independent Core labs
12. N=143 Subjects
13. N=143 Lesions
14. 50% < 0.001
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