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COMPARE-1 CLINICAL TRIAL

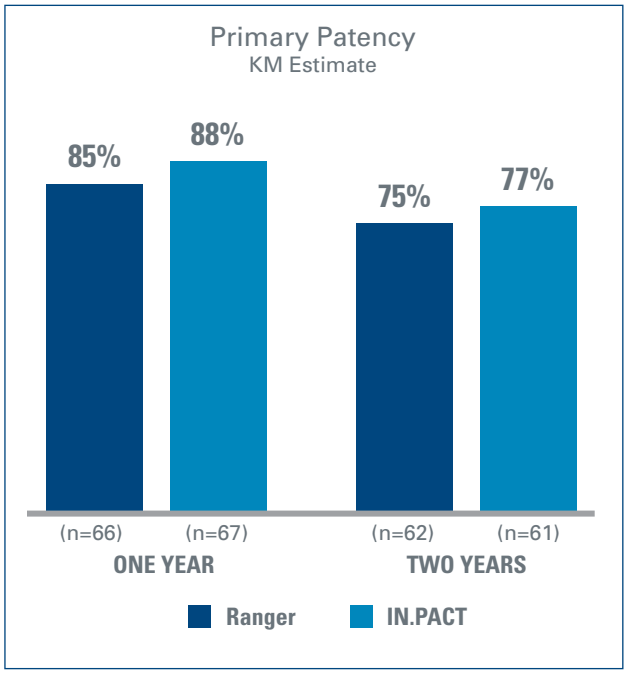
TWO YEAR RESULTS FROM PILOT PHASE PRESENTED AT LINC 2019[1]

TRIAL DESIGN:

WORLD'S FIRST Head-to-Head Prospective, **RANDOMIZED (1:1) CONTROLLED** Trial comparing the lower dose Paclitaxel RANGER DCB (2 µg/mm^2) to the higher dose Paclitaxel IN.PACT DCB (3.5 µg/mm^2)

TWO YEAR RESULTS:

Similar Patency (p=0.57*), with significantly less drug



The new generation, lower dose, Ranger DCB demonstrated similar Patency with significantly less drug compared to the higher dose IN.PACT DCB.

[1]Results from the 150 patient pilot phase. Overall trial will enroll up to 414 patients.
*p-value based on log-rank test

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TRIAL DETAILS

OBJECTIVE:

To compare two different Paclitaxel coated balloons (with different coatings and different Paclitaxel dose density) in the treatment of high grade stenotic or occluded lesions in SFA and/or PPA in PAD patients with Rutherford class 2-4.

TRIAL DESIGN:

- Prospective, multicenter, randomized trial
- Randomization 1:1
- Phase 1: Pilot Study (150 patients)
- Phase 2: Extension (up to 414 patients) for testing of a formal non-inferiority hypothesis
- Stratification according to lesion length
- Follow-up clinical visits at 6, 12, 24 months

	Ranger™	IN.PACT™
Drug Dose	2.0 µg/mm²	3.5 µg/mm²
Longest Length Available	200 mm	150 mm
Platform	Sterling™	Admiral™ or Pacific™
Excipient	TransPax™	Urea

BASELINE CHARACTERISTICS	Ranger™ (n=74)	IN.PACT™ (n=76)	p-value
Total Occlusions	39%	45%	0.5
Total Occlusion Length	111 mm	95 mm	0.5
Target Lesion Length	117 mm	122 mm	0.8
Moderate to Severe Calcification	58%	61%	0.7*
Diabetics	34%	37%	0.7

* p-value includes all categories of calcification

KEY ENROLLMENT CRITERIA:

- Rutherford 2, 3 or 4
- Stenotic, restenotic or occlusive lesions (≥ 70% stenosis) in the native non-stented SFA/PPA
- No prior treatment with drug coated balloons or drug-eluting stents in the treated limb
- Lesion ≤ 300 mm, RVD ≥ 4 mm and ≤ 6.5 mm

DEFINITIONS:

Patency — Core lab adjudicated (12 months):

Efficacy: patency rate after one year defined as absence of clinically driven Target Lesion Revascularization (due to symptoms and drop of ABI of ≥ 20% or > 0.15 when compared to post-procedure) or restenosis with Peak Velocity Ratio > 2.4 evaluated by Duplex Ultrasound

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