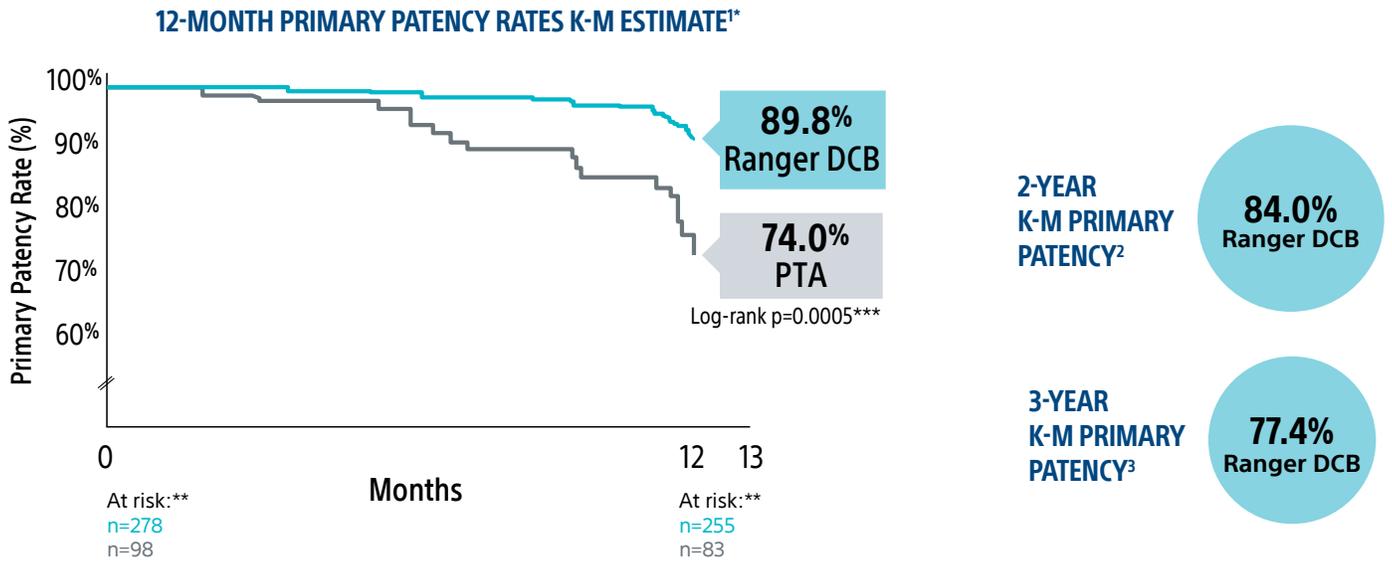


# RANGER II SFA PIVOTAL TRIAL

Prospective, Multi-Center, Randomised Controlled Trial  
Ranger™ Drug-Coated Balloon vs. Uncoated Balloon (3:1). Follow-up through 5-Years



**Ranger DCB demonstrated exceptional outcomes at 1, 2, and 3 years.**



\* Kaplan-Meier Estimate: Primary patency as determined by duplex ultrasound (DUS) Peak Systolic Velocity Ratio (PSVR) is  $\leq 2.4$  at the 12-month follow-up visit, in the absence of clinically driven TLR or bypass of the target lesion.

\*\* At risk denotes the number of subjects entered in the calculation at the time interval.  
\*\*\* Logrank p-value compares the entire K-M curves from time zero to full 1-year follow-up.

## Ranger DCB demonstrated durability, with low reintervention rates through 4 years

### K-M FREEDOM FROM CD-TLR

**94.5% at 1-Year<sup>†</sup>**  
More than 9 in 10 patients did not need reintervention at 1 year



**78.7% at 4-years<sup>‡</sup>**  
Nearly 8 in 10 patients did not need reintervention at 4 years



<sup>†</sup>Subjects at risk at day 365=255 subjects  
<sup>‡</sup>Subjects at risk at day 1460=184 subjects

<sup>1</sup> RANGER II SFA RCT 1-Year Results published in JACC:CI. doi.org/10.1016/j.jcin.2021.03.021  
<sup>2</sup> RANGER II SFA RCT 2-Year Results presented by Ravish Sachar, MD. VIVA 2021  
<sup>3</sup> Latest RCT update presented by Marianne Brodmann, MD at LINC 2023, Tuesday 06-June Main Arena 1 09:45 - 09:50

## 1-YEAR PRIMARY ENDPOINT RESULTS<sup>1</sup>

	Ranger™ DCB (n=278)	PTA (n=98)	p-value
Primary Safety Endpoint (Freedom from MAE)	94.1% (241/256)	83.5% (76/91)	$P_{\text{non-inferiority}} < 0.0001$
Primary Effectiveness Endpoint (Binary Primary Patency)	82.9% (194/234)	66.3% (57/86)	0.0017

## BASELINE PATIENT & LESION CHARACTERISTICS

	Ranger™ DCB (n=278)	PTA (n=98)	p-value
Age (Year)	70.6	69.1	0.1887
Women	37.8%	31.6%	0.2769
Smoking History			0.0303
Current/Previous	31.3%/54.0%	45.9%/38.8%	N/A
Never/Unknown	14.4%/0.4%	15.3%/0.0%	N/A
Diabetes Mellitus	42.4%	43.9%	0.8055
Lesion Length (mm)	82.5	79.9	0.6551
Moderate Calcium (PACSS Grade 3)	36.3%	52.0%	0.0064
Severe Calcium (PACSS Grade 4)	11.5%	10.2%	0.7240
100% (Occlusion)	18.3%	29.6%	0.0193

## 1-YEAR KEY RESULTS<sup>1</sup>

	Ranger™ DCB (n=278)	PTA (n=98)	p-value
CD-TLR	5.5%	16.5%	0.0011
K-M All-Cause Mortality	1.9%	2.1%	0.8794

## 2-YEAR KEY RESULTS<sup>2</sup>

	Ranger™ DCB (n=278)	PTA (n=98)	p-value
K-M Freedom from TLR	87.4%	79.5%	0.0316*
Mod/Sev Calcium Subgroup K-M Freedom from TLR	90.9%	79.6%	0.0246*
CTO Subgroup K-M Freedom from TLR	85.6%	62.8%	0.0172*
All-Cause Mortality	5.7%	3.2%	0.4218

\*Log-rank p-value compares the entire K-M curves from time point zero to day 730 (full 2-year annual visit mark).

## 3- AND 4-YEAR KEY RESULTS<sup>3</sup>

	Ranger™ DCB (n=278)	PTA (n=98)	p-value
<b>3-YEAR RESULTS</b>			
K-M Primary Patency	77.4%	73.5%	p=0.2555
<b>4-YEAR RESULTS</b>			
All-Cause Mortality	14.0% (39/278)	12.2% (12/98)	p=0.6574
K-M Freedom from CD-TLR	78.7%	74.5%	p=0.2108
Major Amputation	0.0%	0.0%	p-undefined

<sup>1</sup>RANGER II SFA RCT 1-Year Results published in JACC:CI. doi.org/10.1016/j.jcin.2021.03.021

<sup>2</sup>RANGER II SFA RCT 2-Year Results presented by Ravish Sachar, MD. VIVA 2021

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