

# **SPORTS Trial**

Investigator-Sponsored<sup>1</sup>, Core-lab Adjudicated, Randomized Controlled Trial Evaluating Drug-Eluting Stent or Drug-coated balloons versus primary bare nitinol stent application in long SFA lesions



### **OBJECTIVE**

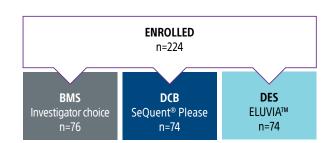
Compare angiographic and clinical outcomes of TASC C/D SFA lesions after treatment with BMS v. DCB v. DES

### **TRIAL DESIGN**

Investigator-sponsored | Prospective | Core-lab adjudicated | Multi-center | Three-arm randomization (1:1:1) of BMS v. DCB v. DES

#### **KEY INCLUSION CRITERIA**

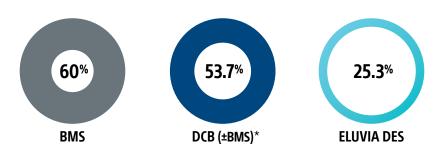
SFA/PPA lesion lengths at least 130mm (treatment length  $\geq$  150mm) | Rutherford classes 2–4 | Diameter stenosis  $\geq$  70%



# Eluvia DES Proved Statistically Superior to BMS in Long, Complex Lesions

- Significantly less in-lesion diameter stenosis at 1 year for Eluvia vs BMS (p<0.0001)</li>
- DCB was non-inferior to BMS in terms of diameter stenosis at 1 year.

## 1-YEAR ANGIOGRAPHIC DIAMETER STENOSIS



# Eluvia DES Confirmed Superior Primary Patency Results Over 24 Months<sup>2</sup>

#### 1.0 88.2% Eluvia DES 75.7% 0.8 Eluvia DES event-free probability 68.4% DCB 0.6 52.1% DCB 50.0% BMS 0.4 33.0% 0.2 DES v. DCB: log-rank p-value < 0.05 DES v. BMS: log-rank p-value < 0.05 DCB v. BMS: log-rank p-value < 0.05 0.0 RMS 62 60 0 182 365 547 730 Days to loss of primary patency

1- AND 2-YEAR PRIMARY PATENCY

 $Calculated \ by \ Kaplan-Meier \ curve \ time \ to \ loss \ of \ primary \ patency \ defined \ as \ ultrasound-derived \ peak \ systolic \ velocity \ ratio \ of \ < 2.4 \ or \ TLR$ 

DES (Eluvia DES)

— DCB (SeQuent Please OTW)

BMS (Bare Metal Stent)

<sup>\*</sup> DCB in SPORTS trial was B. Braun SeQuent® Please Drug-Coated Balloon

<sup>1.</sup> Tepe, G. SPORTS Trial: Drug Eluting Stent or Primary Bare Nitinol Stent Application versus Drug Coated Balloons in Long SFA Lesions. Presented at TCT 24 Oct 2023.

2. Tepe, G. SPORTS Trial: Drug Eluting Stent or Primary Bare Nitinol Stent Application versus Drug Coated Balloons in Long SFA Lesions. Presented at Charing Cross 23 Apr 2025.

# High Rate of Bail-Out Stenting in DCB Arm

In long, complex lesions,

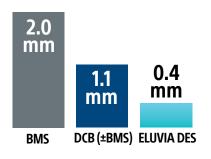
**58%** 

of lesions treated with a DCB required a bail-out BMS which provided no additional clinical benefit versus BMS alone.

### **1-YEAR LATE LUMEN LOSS**

# 2-YEAR FREEDOM FROM CD-TLR

Late Lumen Loss and Freedom from CD-TLR Differed Statistically Across Groups, Favoring Eluvia DES



63.8% 75.0% 85.5%

BMS DCB (±BMS) ELUVIA DES

p<0.0001

K-M, p<0.05

### **BASELINE CHARACTERISTICS**

Patient Characteristics	<b>BMS</b> n=76	<b>DCB</b> n=74	<b>DES</b> n=74
Age (Years)	67	70	68
Male Gender (%)	72	66	60
Diabetes Mellitus (%)	26	30	23
Renal Disease (%)	3	12	8
Current Smoker (%)	58	60	55

Lesion Characteristics	<b>BMS</b> n=76	<b>DCB</b> n=74	<b>DES</b> n=74	p-value
Mean Lesion Length (mm)	227	221	235	0.57
Occlusion (%)	74	70	85	0.08
Occlusion length (mm)	151	175	179	0.18
RVD (mm)	5.2	5.0	5.3	0.01
MLD in lesion (mm)	0.3	0.4	0.2	0.18
Mod/Severe Calcification (%)**	67.1	71.7	58.1	0.36
Diameter stenosis in lesion (%)	94.2	92.6	96.8	0.10

ELUVIA Drug-Eluting Vascular Stent System

**CAUTION:** The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France. Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.



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<sup>\*\*</sup> PACSS Grade 3/4 may be considered moderate to severe calcification