Preliminary 1-year outcome of the KANSHAS 1 study of the novel KANSHAS drug-coated balloon for treatment of femoropopliteal occlusive disease: the first-in-human study

Michael Lichtenberg, MD, FESC
on behalf of the KANSHAS 1 study investigators
Tepe G, Müller-Hülsbeck S, Deloose K,
Verbist J, Goverde P, Zeller T

Disclosure

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

Affiliation/Financial Relationship	Company

1. **Honoraria for lectures**: CR Bard, Veniti, AB Medica, Volcano, Optimed GmbH, Straub Medical, Terumo, Biotronik, Veryan
2. **Honoraria for advisory board activities**: Veniti, Optimed GmbH, Straub Medical, Biotronik, Veryan, Boston Scientific
3. **Participation in clinical trials**: Biotronik, CR Bard, Veryan, Straub Medical, Veniti, TVA Medical, Boston Scientific, LimFlow
4. **Research funding**: Biotronik, Boston Scientific, Veryan, Veniti, AB Medica

Objective

- Drug coated balloon therapy has demonstrated a higher effectiveness compared to standard PTA and has been widely accepted as a valuable treatment option for patients with femoropopliteal disease.

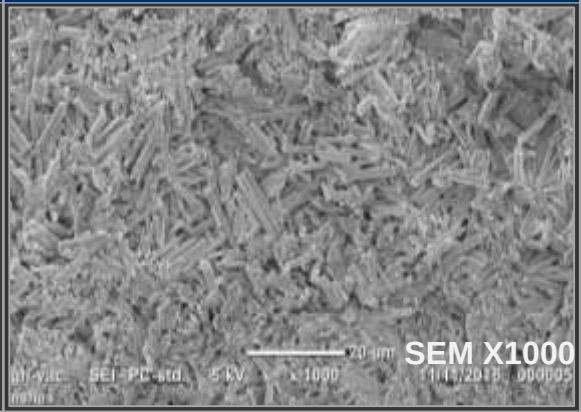
- KANSHAS drug coated balloon has been developed to address some limitations of first generation DCBs related to coating integrity.

- This KANSHAS 1 first-in-human study aims at investigating safety profile and therapeutic advantages of the novel KANSHAS DCB in treatment of de novo femoropoliteal lesions.

Kanshas DCB device

Specification

- Drug: Paclitaxel (3.2µg/mm^2)
- Balloon diameter: 4.0 – 7.0 mm
- Catheter length: 150 cm
- Nominal pressure: 8 atm (RBP 10-14 atm)
- Excipient: L-Serine Ethyl Ester HCl
- Balloon length: 40 – 200 mm
- Compatible GW size: 0.018”
- Rapid exchange type

Uniform coating	Crossing profile	Micocrystaline Paclitaxel
	 * Crossing Profile of Ø 6.0mm balloon	

CE marked since June 2018

KANSHAS 1 study overview

To assess safety and efficacy of the Kanshas drug coated balloon catheter in the treatment of de novo lesions in the superficial femoral and/or popliteal arteries

Prospective, multi-center, open, single arm study with 2-year follow-up period

50 patients enrolled at 6 sites in Germany and Belgium from April 2017 to January 2018

- Karolinen-Hospital: Klinikum Arnsberg
- Universitäts-Herzzentrum Freiburg-Bad Krozingen
- Ev Luth Diakonissenanstalt zu Flensburg Zentrum für Gesundheit und Diakonie
- RoMed Klinikum Rosenheim

- AZ St. Blasius Dendermonde
- Imelda Ziekenhuis Bonheiden
- ZNA Stuivenberg Antwerpen

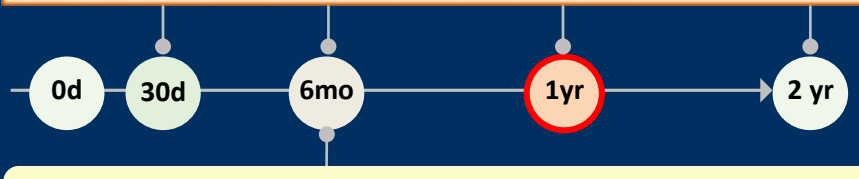
Enrollment completed and FUs are on-going

Study management

- Steering Committees
- Clinical Event Committee (CEC)
- Data Monitoring Committee
- Angiographic Core Laboratory (BIDMC)
- Ultrasound Core Laboratory (Vascore)
- Monitors (Genae, Terumo Europe)
- Managed and sponsored by Terumo Europe

100% source data verification and independent core labo assessment
Adverse events adjudication by CEC

Clinical Follow-up of 50 patients



Primary endpoint
Freedom from Composite Safety* at 6 months

***Defined as freedom from device- and procedure-related deaths through 30 days, freedom from target limb amputation, and clinically-driven target lesion revascularization (TLR) through 6 months**

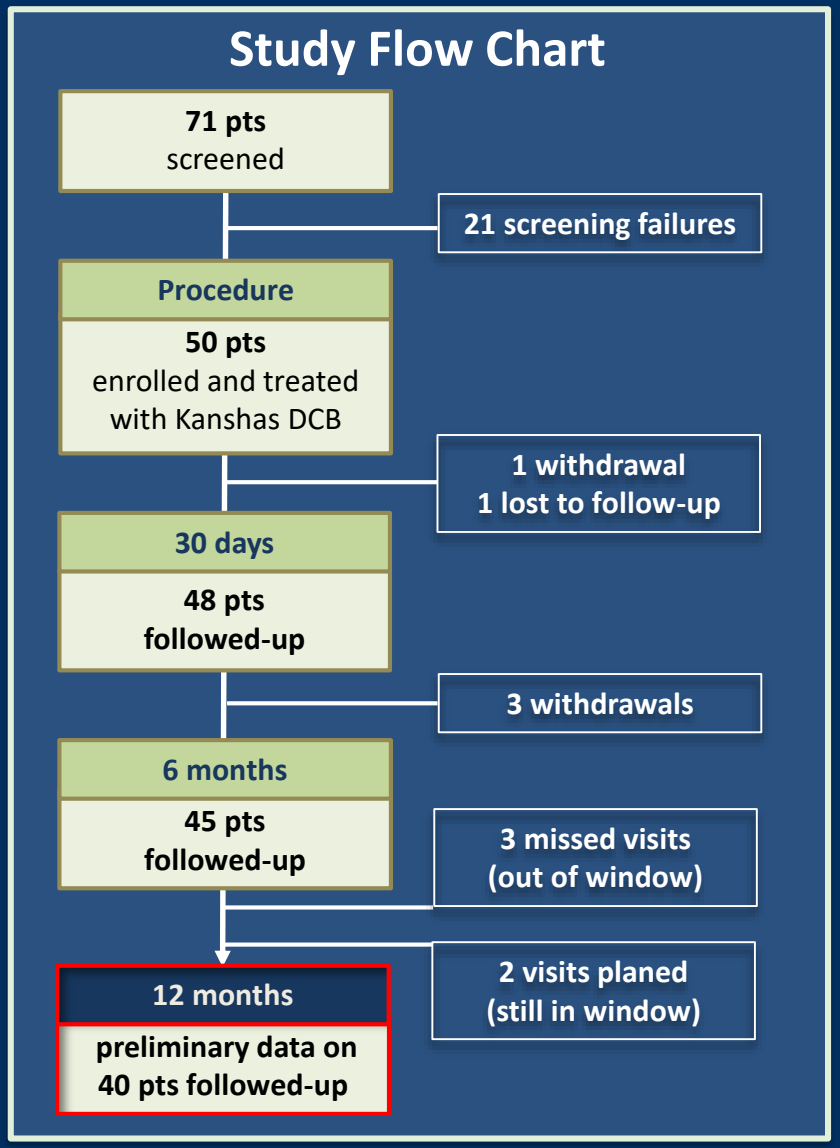
Eligibility and Patient disposition

Main Inclusion Criteria:

- Clinically significant symptomatic leg ischemia, requiring treatment of the **SFA and/or PA**
- **Rutherford Clinical Category of 2-4**
- **Resting ABI of < 0.9 or abnormal exercise ABI**
- **Cumulative lesion length 4-15 cm**
- Clinically and hemodynamically significant **de novo stenosis (>70% stenosis) or occlusion including P3 segment**
- Patent inflow artery (≥50% DS)
- At least one patent outflow artery

Main Exclusion Criteria:

- In-stent restenosis
- **Vessel injuries after predilatation; flow-limiting dissection, requiring stenting, or perforation**
- Subintimal recanalization
- **Severe calcification** in the target lesions that precludes endovascular treatment
- Previous treatment with DCB or DES in target vessel



SFA: superficial femoral artery, PA: popliteal artery, ABI: ankle-brachal index, DS: diameter stenosis, DCB: drug-coated balloon, DES: drug eluting stent

Baseline and lesion characteristics

Patients	N=50
Age, years	69.0 ± 10.5
Male	34 (68.0)
Hypertension	43 (86.0)
Hyperlipidemia (n=49)	36 (73.5)
Diabetes Mellitus	18 (36.0)
Smoker (n=49)	
Current	21 (42.9)
Previous	19 (38.8)
Ischemic heart disease[a]	17 (34.0)
History of PAD (n=49)	23 (46.9)
Renal insufficiency	4 (8.0)
COPD	6 (12.0)
Cerebrovascular disease[b]	6 (12.0)
Rutherford category	
2	8 (16.0)
3	39 (78.0)
4	3 (6.0)
ABI (n=48)	0.67 ± 0.14

Target lesions[c]	N=50
Lesion location	
SFA proximal	1 (2.0)
SFA mid	25 (50.0)
SFA distal	21 (42.0)
Popliteal proximal	9 (18.0)
Popliteal mid	8 (16.0)
Popliteal distal	2 (4.0)
Cumulative lesion length, mm	88.6 ± 36.5
Single lesion	45 (90.0)
Multiple lesion[d]	5 (10.0)
Reference vessel diameter, mm	5.4 ± 0.6
Diameter stenosis, %	91.0 ± 9.4
Calcification	
None	21 (42.0)
Mild	19 (38.0)
Moderate	9 (18.0)
Severe	1 (2.0)
Total occlusion	15 (30.0)
Ipsilateral inflow lesion	4 (8.0)
Successful treatment	4/4 (100.0)
Patent run-off vessels	
1 vessel	13 (26.0)
2 vessels	13 (26.0)
3 vessels	24 (48.0)

Data are shown as mean ± SD or n (%).
COPD: chronic obstructive pulmonary disease, PAD: peripheral artery disease
a: History of myocardial infarction, angina pectoris, or previous percutaneus or surgical revascularization.
b: Known carotid artery disease or history of minor or major stroke or transient ischemic attack. c: Assessed by visual estimate.
d: Multiple focal lesions separated by a gap of ≤30mm were counted as one lesion.

Procedure characteristics and outcomes

Procedural characteristics[a] (n=50)	
Pre-dilation	48 (96.0)
Total inflated length, mm	72.1 ± 26.7
Balloon/ artery ratio	0.86 ± 0.10
Residual DS, %	35.6 ± 22.3
DCB per lesion (58/50)	1.2 ± 0.4
Balloon transit time, sec	44.3 ± 54.7
Total inflated length, mm	117.0 ± 48.9
Balloon/ artery ratio	1.04 ± 0.07
Maximum pressure, atm	10.0 ± 1.7
Inflation time/balloon, min	3.2 ± 0.7
Post-dilation	17 (34.0)
Total inflated length, mm	81.8 ± 28.3
Balloon/ artery ratio	0.97 ± 0.11
Stenting*	14 (28.0)
Due to flow-limiting dissection	1 (2.0)
Due to residual stenosis >50%	3 (6.0)

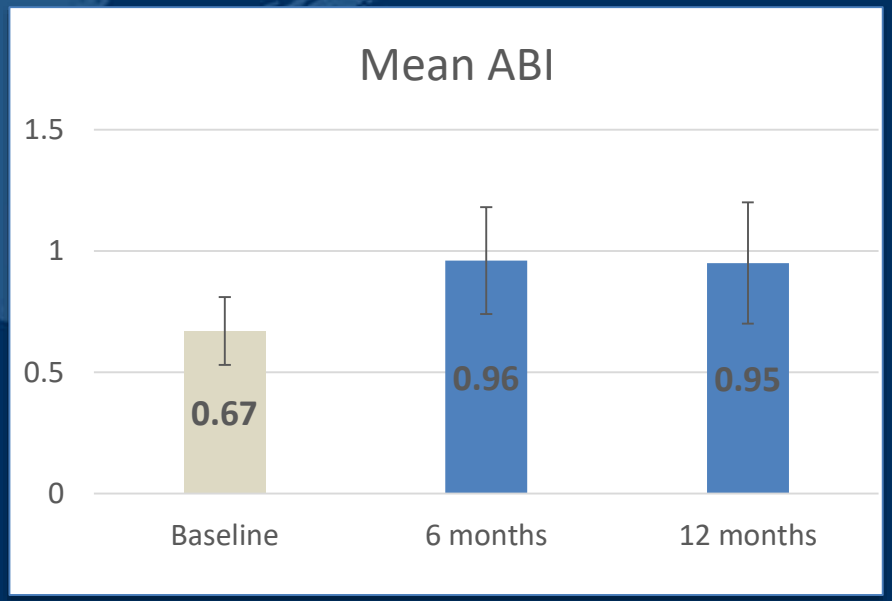
Procedural outcomes	
Device success**	58 (100.0)
Residual diameter stenosis[a] , %	11.2 ± 7.8
Length of hospital stay, days	1.7±0.6

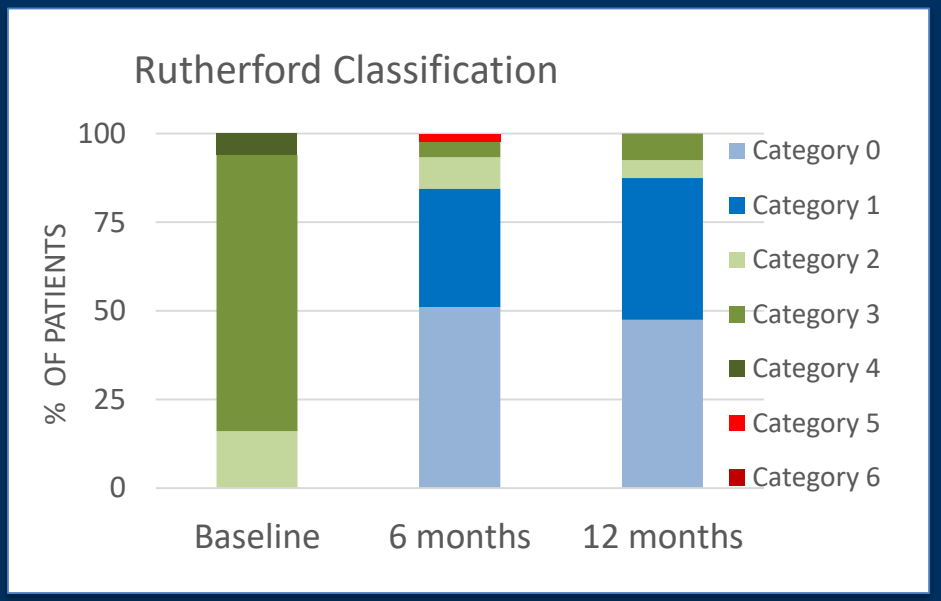
Data are shown as mean ± SD or n (%)
a: Assessed by visual estimate.
* After unsuccessful post-dilatation for a residual stenosis >50% or significant dissection after the use of Kanshas DCB, bailout procedures with commercially available nitinol stents were allowed at the discretion of the operator.
** Device success defined as no device malfunction

6 and 12 month outcomes

Hemodynamic outcomes		
	6 months	12 months
ABI	0.96±0.22 (n=45)	0.95±0.25 (n=39)
ABI change vs baseline (matched)	0.28±0.24 (n=43)	0.25±0.16 (n=37)

Rutherford class change from baseline (matched)	
6 months (n=45)	
Improvement	42 (93.3)
No change	2 (4.4)
Worsening	1 (2.2)
12 months (n=40)	
Improvement	37 (92.5)
No change	2 (5)
Worsening	1 (2.5)



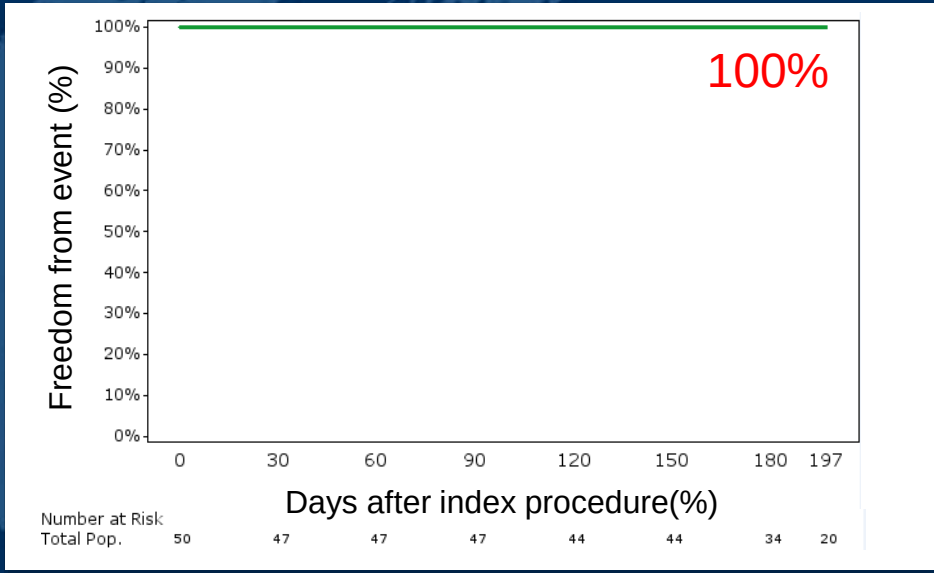


Data are shown as mean ± SD or n (%),

Primary Endpoint

Defined as:

Freedom from device- and procedure-related deaths through 30 days, freedom from target limb amputation, and clinically-driven target lesion revascularization (CD-TLR) **through 6 months**



6 months follow up	
Device-/Procedure-related deaths	None
Target limb amputation	None
CD-TLR	None

No device and procedure related Severe Adverse Events (SAE) have been reported up to 6-month FU

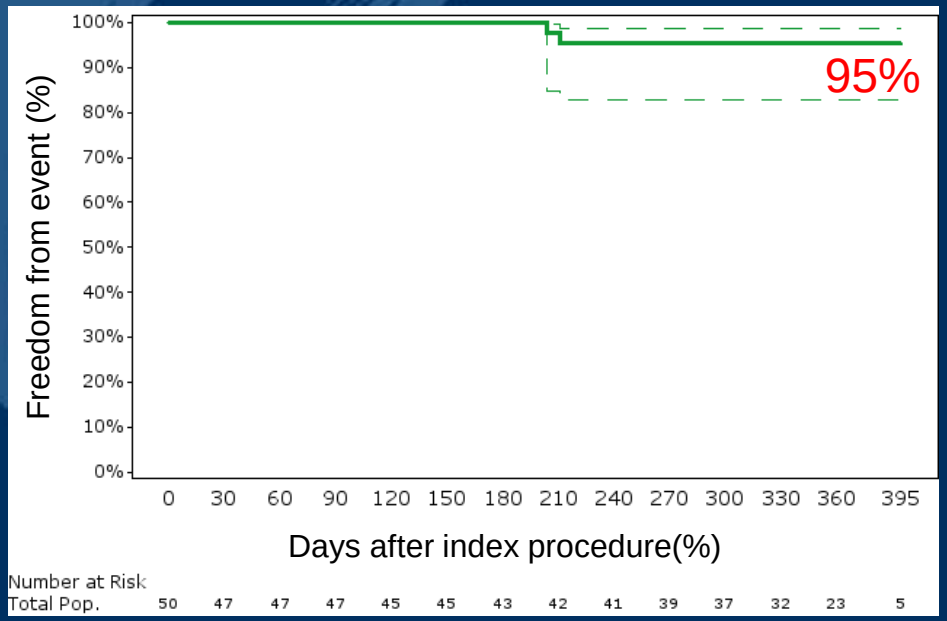
Secondary Endpoint

Major adverse event (MAE) rate at 12 months

-Preliminary Efficacy data-

Defined as:

Freedom from all death, target limb amputation, and clinically-driven target lesion revascularization (CD-TLR) through 12 months



12 months follow up	
Any deaths	None
Target limb amputation	None
CD-TLR	2/40 (5%) at (1) after 204 days (2) after 211 days

Conclusions

DCB angioplasty for de novo femoropopliteal artery lesions with the novel KANSHAS DCB was safe and efficient through 12 months after procedure.

Clinical and hemodynamic improvement at 12 months was achieved in the great majority of patients after KANSHAS DCB treatment.

Preliminary 1-year outcome of the KANSHAS 1 study of the novel KANSHAS drug-coated balloon for treatment of femoropopliteal occlusive disease: the first-in-human study

Michael Lichtenberg, MD, FESC
on behalf of the KANSHAS 1 study investigators
Tepe G, Müller-Hülsbeck S, Deloose K,
Verbist J, Goverde P, Zeller T