Luminor® DCB in femoropopliteal lesions –

EffPac trial results and soLo DCB study design

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Disclosure

Speaker‘s name: Marcus Thieme

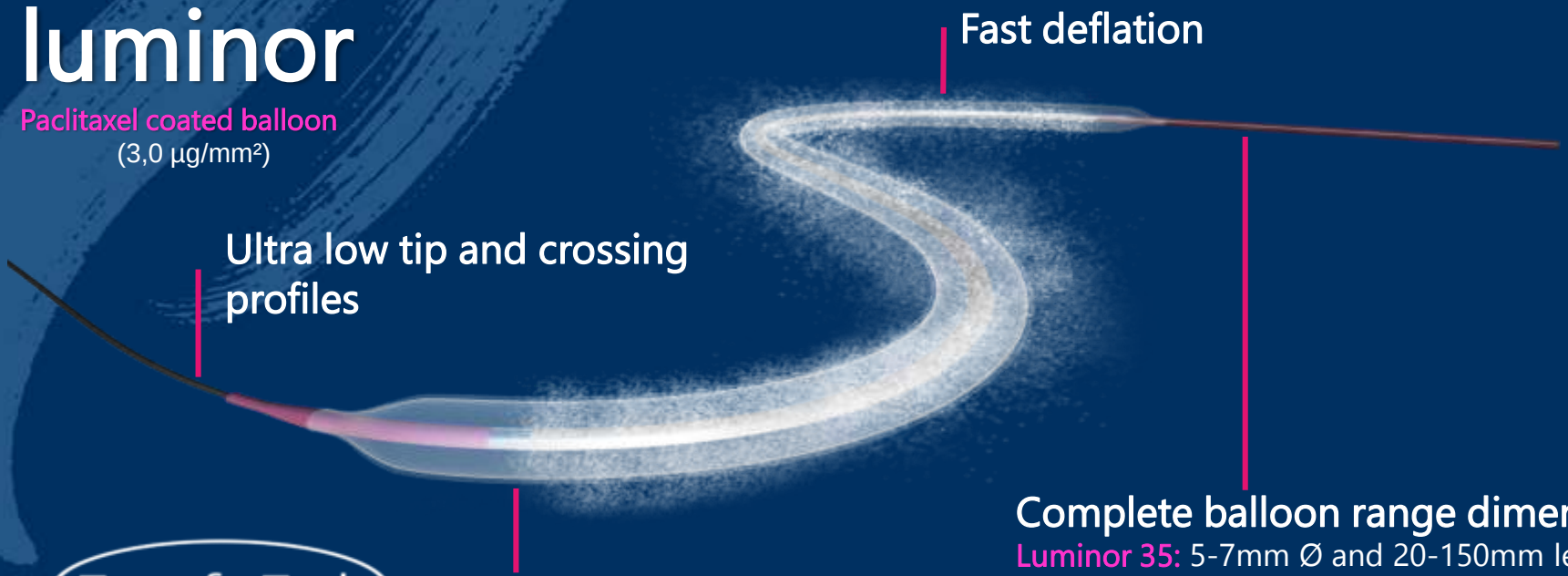
I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☐ I do not have any potential conflict of interest

luminor

Paclitaxel coated balloon
(3,0 µg/mm²)



Fast deflation

Ultra low tip and crossing profiles

Innovative and UNIQUE nanotechnology coating

Complete balloon range dimensions

Luminor 35: 5-7mm Ø and 20-150mm length
Luminor 18: 2-8 mm Ø and 20-200mm length
Luminor 14: 1.5-4mm Ø and 40-200mm length

luminor

UNIQUE nanotechnology coating

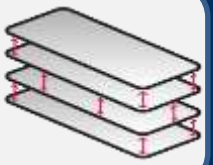
Ultrasound

Spray Technology

Dosage of uniform diameter nanodrops by ultrasonic deposition

Multi-layer technology

- Coating durability during the procedure
- No cracking



TransferTech

Proprietary nanotechnology dosage system for an **uniform, flexible** and **ultrathin coating**

Excipient

- Organic ester
- Biocompatible
- Lipophilic

Paclitaxel

- Lipophilic
- Inhibition of stenosis
- Specific cellular receptors

Dry-off

- Microcrystalline structure
- Optimal drug transfer to the vessel wall within 30-60s seconds

EffPac Trial

Investigator-initiated Multicenter Randomized Controlled Trial
to assess the

Effectiveness of Paclitaxel-coated Luminor® Balloon Catheter
vs.
Uncoated Balloon Catheter

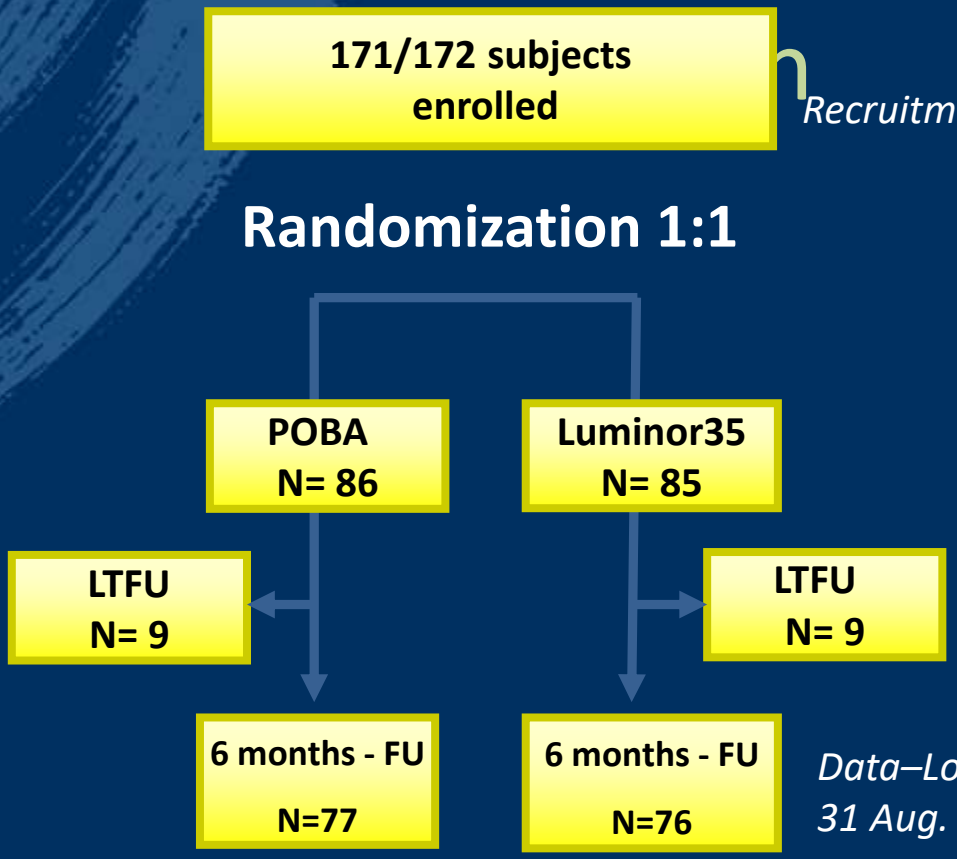
in the Superficial Femoral and Popliteal Arteries to Prevent Vessel Restenosis or Reocclusion

11 Participating Sites

01 Jena	PD Dr. R. Aschenbach, *University Hospital Jena*
02 Leipzig	Prof. Dr. Dierk Scheinert, *University Hospital Leipzig*
03 Bad Krozingen	Prof. Dr. Thomas Zeller, *Heart Center*
04 Hamburg	Dr. S. Sixt, *Angiologikum*
05 München	PD Dr. M. Treitl, *University Hospital*
06 Berlin	Prof. Dr. K. Brechtel, *„Ihre Radiologen"*
07 Sonneberg	Dr. M. Thieme, *Medinos Clinic*
08 Karlsbad	Prof. Dr. E. Blessing, *SRH-Clinic*
09 Heidelberg	Dr. B. Vogel, University Heidelberg
10 Arnsberg	Dr. M. Lichtenberg, *Clinic Arnsberg*
11 Kusel	Dr. P. von Flotow, *Westpfalz Clinic*

Trial Design and Endpoints

Endpoints		Baseline	6 months	12 months	24 months
Efficacy	Primary	Vessel diameter (mm)	• Late Lumen Loss (LLL)*	-	-
	Secondary		• Freedom from Target Lesion Revascularization (TLR/TVR) • Patency • Change of ABI, Rutherford stage, QoL (WIQ) , EQ-5D		
Safety	Primary		• Major and minor amputation rate at index limb • Mortality, independent of cause		



Recruitment completed on 31 Dec. 2016

Data–Lock–Point for 6 months-FUP on 31 Aug. 2017

Procedural Characteristics

	LUMINOR®	POBA	p value
Vessel preparation: Pre-dilatation performed	100% (84/84)	98.8% (85/86)	1.000
Dissection	37.6% (32/85)	40.7% (35/86)	0.755
Stent rate	15.3% (13/85)	18.8% (16/85)	0.684

Efficacy
Late Lumen Loss - LLL

*** LLL =** difference between the diameters (in mm) at 6 months follow-up and post-procedure

	LUMINOR®	POBA	Difference, 95% CI (LUMINOR® vs. POBA)	p value
LLL 6M (mm)*	0.14 [CI: -0.38; 0.67]	1.06 [CI: 0.54; 1.59]	-0.92 [CI: -1.36; -0.49]	<0.001

* Estimated LLL (Mean, 95% CI) from linear mixed model adjusted for center

Efficacy: Improvement of Rutherford after 6M

Improvement of Rutherford Stages	LUMINOR®	POBA
Deterioration of 1 stage	1.4% (1/74)	0% (0/82)
No improvement	13.5% (10/74)	25.0% (18/82)
Improvement of 1 stage	12.2% (9/74)	20.8% (15/82)
Improvement of 2 stages	28.4% (21/74)	26.4% (19/82)
Improvement of 3 stages	44.6% (33/74)	27.8% (20/82)

Significantly higher improvement of LUMINOR® compared to POBA (p=0.021)

Efficacy: Target Lesion Revascularization (TLR)

	LUMINOR®	POBA	Relative Risk, 95% CI (LUMINOR® vs. POBA)	Number needed to treat (NNT)	p value
TLR 6M (%)	1.3 (1/76)	17.1 (13/76)	0.082 [CI: 0.012; 0.560]*	7	<0.001

*Relative Risk Reduction (RRR) = 91.8%, Cochran-Mantel-Haenszel estimate, adjusted for center

Efficacy: Target Lesion Revascularization (TLR)

Study	DCB 6 mo TLR (%)	Control 6 mo TLR (%)
EFFPAC 2017 Luminor (iVascular)	**1.3 (1/76)**	**17.1 (13/76)**
THUNDER Tepe et al. 2008 Paccocath coating	4.2 (2/48)	37.0 (20/54)
AcoArt I Trial Jia et al. 2016 Orchid (Acotec)	6.1 (6/99)	38.8 (38/98)
FEMPAC Werk et al. 2008 Paccocath DCB	6.7 (3/45)	33.3 (14/42)
CONSEQUENT 2017 SeQuent Please (B. Braun)	8.9 (7/78)	30.7 (23/75)
RANGER Bausback et al. 2017 Ranger DCB	5.6 (4/71)	12.0 (4/34)
BIOLUX P-I Trial Scheinert et al. 2015 Passeo-18 Lux (Biotronik)	3.8 (1/26)*	4.2 (1/24)*

*Kaplan-Meier estimates, clinically driven TLR

soLo-DCB Study

Design:

A prospective, global, multi-center, single-arm, real-world, observational study investigating the clinical use and safety of the Luminor® Paclitaxel-coated balloon

Objective:

To demonstrate safety and assess the clinical use and outcomes of the Luminor® Paclitaxel-coated balloon in a heterogeneous patient population in real-world clinical practice

Sponsor: Regiomed Vascular Center Sonneberg, Germany

Study Design and Endpoints

Enrollment

- Up to 500 patients at 15 sites in Europe
- Follow-up at 6 weeks (by phone); 6, 12 and 24 months (Duplex)

Inclusion

- Femoropopliteal lesions, treatable with Luminor ® DCB per current IFU
- Male or non-pregnant female ≥ 18 years
- Rutherford class ≤ 4
- More than 70% stenosis or obstruction of femoropopliteal arteries
- At least 1 patent native outflow artery

Registry Design and Endpoints

Endpoints			6-months	12-months	24-months
Efficacy	Primary		• Freedom from Target Lesion Revascularization (TLR/TVR)		
	Secondary		• Patency • Change of ABI, Rutherford stage, QoL (WIQ) , EQ-5D		
Safety	Primary		• Major and minor amputation rate at index limb • Mortality		

Conclusions

- The LUMINOR® Paclitaxel-coated balloon catheter demonstrates to be clinically highly effective and safe in inhibiting restenosis compared to POBA.
- The innovative coating technique matters and is shown not only in the patency and TLR data, but also in an improvement of the Rutherford stage.
- The results of the EffPac study allow direct comparison to other already completed RCTs applying Paclitaxel-coated balloons from different manufacturers in the same target vessel.
- soLo-DCB study will get the insights from a larger patient population.

EffPac-Trial results of 12-months follow-up will be presented on March 2018.

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