Value of Stellarex DCB (Philips) in BTK and Infrapopliteal Artery Lesions

Gunnar Tepe, MD
RodMed Clinic Rosenheim
Rosenheim, Germany

Background – DCB-BTK Evidence Fails
2 multicenter independently adjudicated Randomized Trials

IN.PACT DEEP N = 358
• no difference between DCB and PTA in any lesion-specific Endpoint @ 1-year
• (Potential) Safety Signal: 3-year Major Amp: 8.8% (DCB) vs 3.6% (PTA) (p=0.050)

BIOLUX P-II N = 72
• Patency Loss: 50.8% vs 45.6% (p=0.908)
• CD TLR: 31.3% vs. 26.9% (p=0.805)
• Major Amp. (CLI subset): 4.3% vs. 7.1% (p=NS)

IN.PACT DEEP
N = 358
• no difference between DCB and PTA in any lesion-specific Endpoint @ 1-year
• (Potential) Safety Signal: 3-year Major Amp: 8.8% (DCB) vs 3.6% (PTA) (p=0.050)

Hypothesis around DCB-BTK RCTs failures
✓ Study design: not selective enough?
✓ Study execution: follow up compliance?
✓ Wrong endpoints?
✓ Burden and complexity of BTK disease underestimated?

DCB Technology
In.Pact Amphirion and Passeo 18 Lux
both examined in a folded (deflated) state

Stellarex Technology Highlights
Low dose paclitaxel, hybrid formulation
Polyethylene Glycol (PEG) high molecular weight excipient

• Sustained drug release (stabilizes) + prompt drug availability and improved coating stability (amorphous)
• High molecular weight — starting, availability, to balloon deformation and slow dissolution with reduced drug loss during tracking
• Natural affinity towards Hydroxylapatite hypothesized to limit ptx washout in presence of calcium
Stellarex Technology Highlights

• Desired drug tissue uptake and retention with similar treatment effect to DCB with 75% higher drug dose [1-2]
• Limited drug particulate embolization [3]

Arterial Pharmaco-Kinetics [1]
Treatment Effect [2]
Particulate loss after transit [2]

1. Superimposed PK curves from different datasets: R.Melder, EuroPCR 2012; Yazdani et.al. Catheterization and Cardivascular Interventions 83:132-140 (2014); data on file at Spectranetics
2. J.F.Granada - Design goals and preclinical evidence of next generation DCB – oral presentation, LINC 2017
3. Number of particulates \( \geq 10\mu m/mm \) of DCB length lost during transit. Data on file at Spectranetics

Stellarex limited particulate embolization

• Independent, physician initiated DCB animal study
• Rabbit model / DCB deployed in Aorta
• 5 different DCB tested x 5 specimens: tot 25 rabbits
• blinded evaluation of ptx particles and dose by HPLC

Pts in Tibials
Pts muscles (global)
Pts remaining on balloon

R.Concas, UNC 2018

Stellarex BTK Clinical Program and Status

BTK trials: ILLUMINATE EU RCT, ILLUMINATE US Pivotal, ILLUMINATE BTK CE Post Market Study, ILLUMINATE IDE RCT + Vessel prep Registry

PI(s)
G. Tepe; B. Gray; M. Razavi; D. Scheinert; M. Lichtenberg

Design
single-arm Randomized DCB vs. PTA + parallel Vessel-prep Registry

N patients / Sites
75 / 10 (EU) 354 (RCT) + 100 (vessel Prep Registry) / 45 Centers (US, EU, Asia Pacific)
75 / 5 (Germany)

Patient population
RCC 3-4-5 RCC 4-5 RCC 4-5

Objective
1) Safety and efficacy of Stellarex BTK as part of CE post-market monitoring
2) Investigate the role of Laser + DCB in non-crossable and/or failed pre-dilatation lesions (Vessel Prep registry)

1) Investigate role of vessel prep with Phoenix atherectomy of BTK lesions with moderate or severe Ca
2) Correlate Angio, Duplex, IVUS Core-lab findings

Prim. Efficacy Endpoint
6 MO Patency + Limb salvage

Status
Enrolling

The importance of DCB deliverability in BTK

• Stellarex shows excellent deliverability across the challenging distal BTK tortuositues

Conclusions

• Stellarex technology engineered to match important requisites for DCB success in above and below the knee
• High transfer efficiency, durable coating with limited drug embolization, excellent balloon deliverability through the BTK vascular bed
• Clinically proven in SFA by robust level 1 evidence
• Currently in clinical trial for BTK