OncoSil MEDICAL

Webinar Presentation

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Targeted Approach • Positive Impact

ASX Code: OSL

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The information contained in this presentation is current as at 11 February 2025.

OncoSil continues to hit material operational targets

Achievements against strategy: financial year to date

Operational

- ✓ Expanded global presence via exclusive distribution agreements in GCC, Egypt and Nordics
- ✓ G-BA approval for fully funded clinical trial in Germany
- ✓ Conformity assessment approval certificates in EU and UK remove post-market restrictions to enable accelerated market access and streamlined commercial operations
- ✓ 1st OncoSil treatment at Instituto Nazionale dei Tumori, Italy strengthens EU footprint
- ✓ TRIPP-FFX and PANCOSIL trials both exceed 75% recruitment

Financial

- ✓ $0.402 million revenue from commercial sales during the six months 31 Dec ‘24 (subject to audit)
- ✓ $8.46 million cash and cash equivalents as at 31 Dec ’24
- ✓ $10.93 million (before costs) raised providing a strengthened cash position and balance sheet
- ✓ $1.05 R&D tax rebate received in Jan ‘25

In detail today

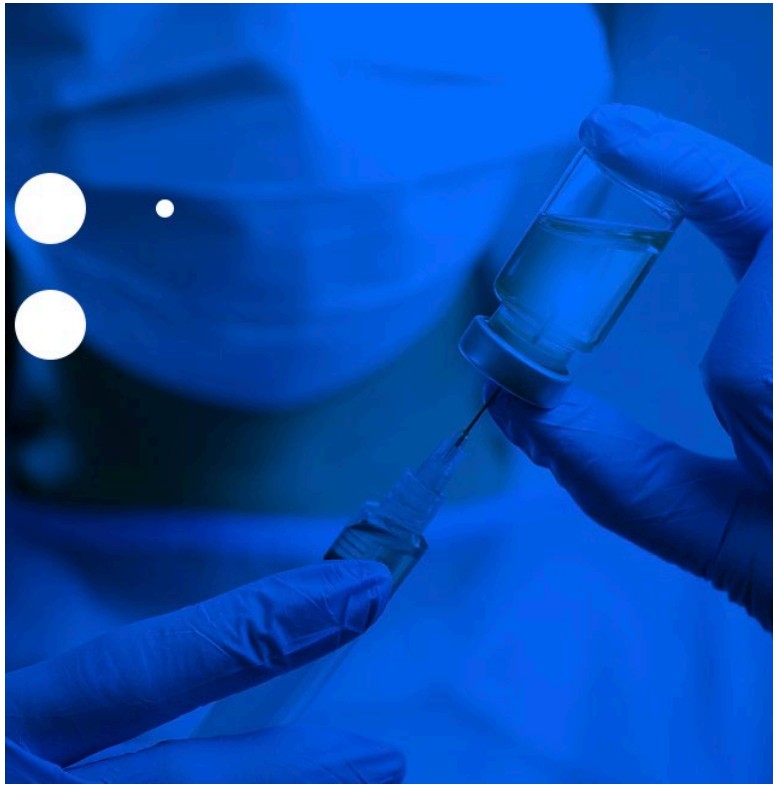
Recent operational achievements and what they mean for strategy

1. **G-BA approval** for testing new treatment method "Endoscopic injection-implantation of 32P-labeled microparticles in unresectable, locally advanced pancreatic tumors" enables fully funded Phase III ("CED") trial. OncoSil device used in trial to be **reimbursed**.

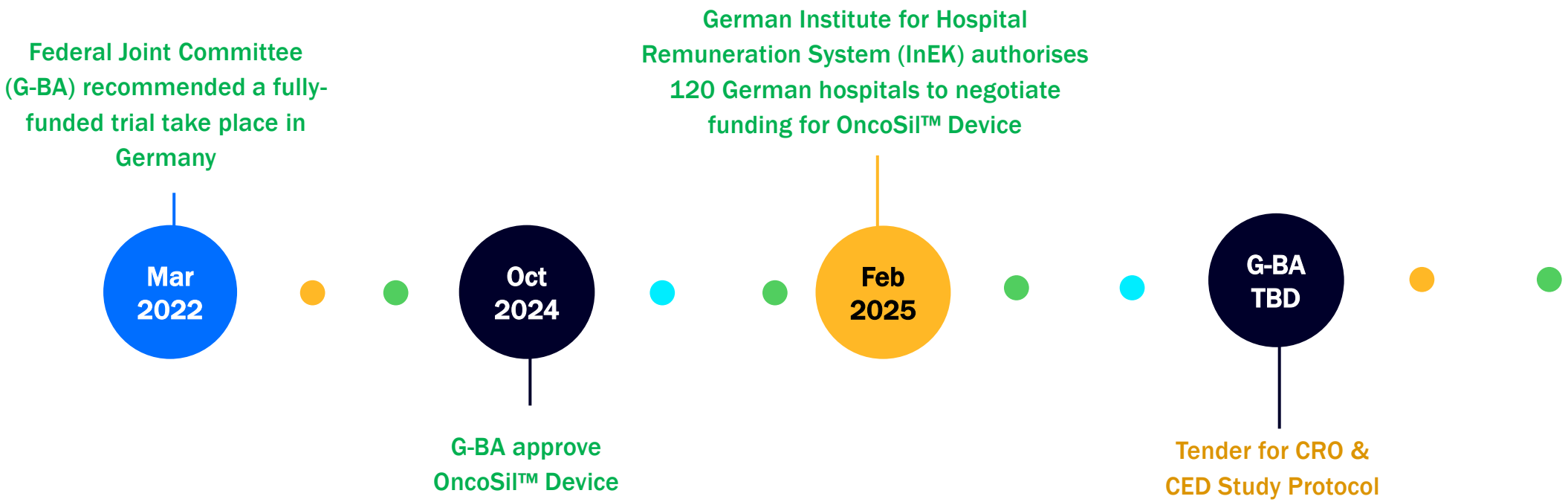
2. Authorisation by the German Institute for the Hospital Remuneration System (**InEK**) for **120 German hospitals** to negotiate funding for the OncoSil™ device underscores growing recognition of OncoSil™ device in German healthcare system and further highlights unmet need

3. Medical Device Regulation (**MDR) EU certification** from BSI (following UK certification received in Oct '24)

4. Next steps for clinical trials: **TRIPP-FFX** (78% recruited) and **PANCOSIL** (80% recruited)



G-BA fully funded trial in Germany

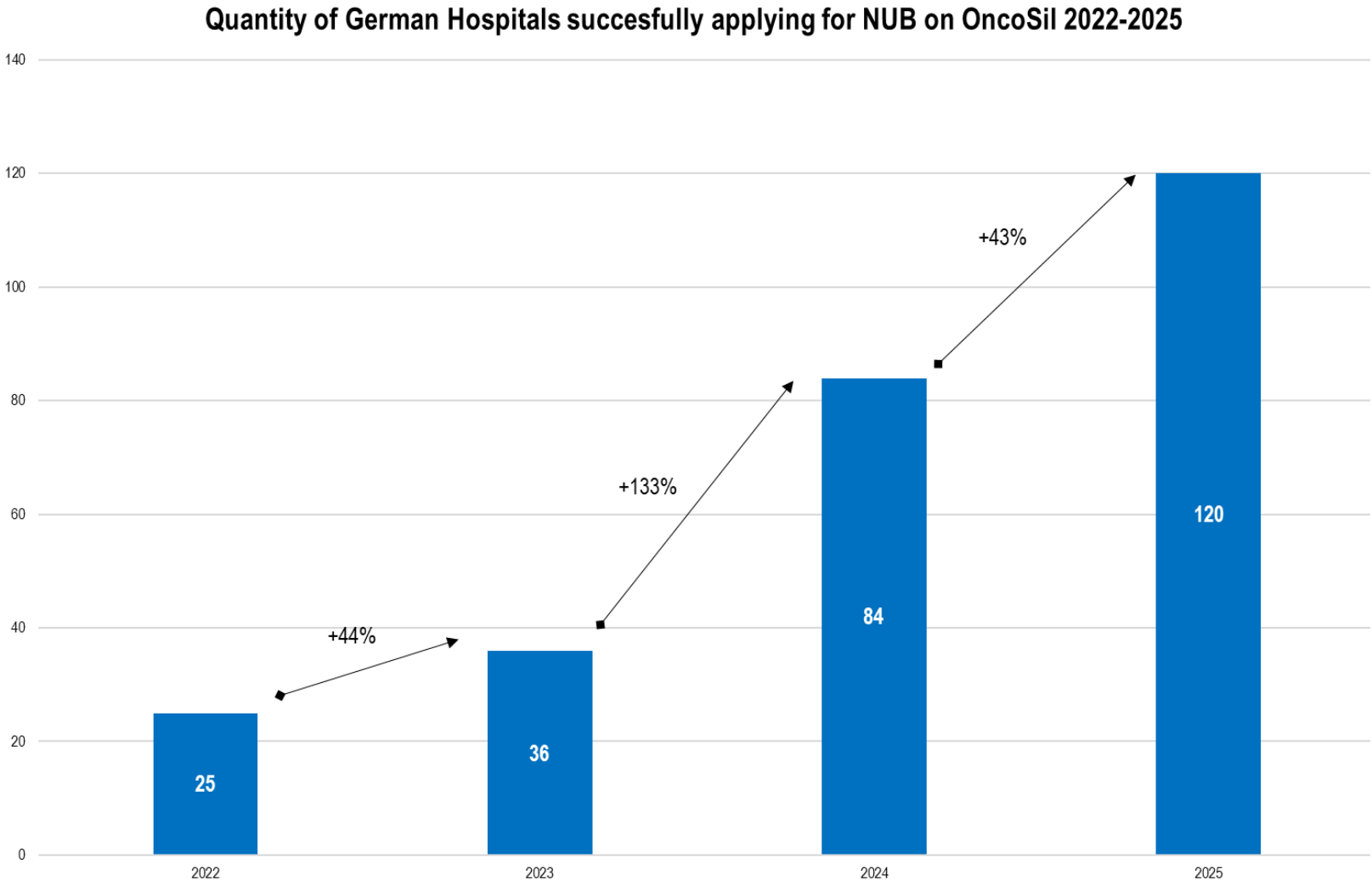


Top 10 German pancreatic cancer centers performed ~2,000 complex surgeries in 2023. These represent OncoSil's primary targets for commercial adoption.

Source: AOK-BV. Mindestmengen-Transparenzliste 16/25

G-BA fully funded trial in Germany

Leading to public insurance reimbursement



Feb 2025: InEK authorized 120 German hospitals to negotiate funding for the OncoSil™ device representing a 43% increase in potential access over 2024 (84 hospitals).

Authorization underscores both the demand in Germany and the growing recognition of the OncoSil™ device in the German healthcare system.

Note: Calendar year

Medical Device Regulation (MDR) certification

Lifts post-market restrictions and paves way for accelerated market access

- ✓ British Standards Institution (BSI) is the EU Notified Body
- ✓ Receipt of MDR removes administrative burden and requirement for ethics committee approval saving six months in new hospital account onboarding:
  - Phosphorus-32 (^{32}P) is the only isotope license required for new hospital accounts. All current hospital sites have required license
  - Up to €2 million over three years can be saved in ethics approval and patient recruitment related costs
- ✓ Follows Oct '24 BSI renewal of UK Conformity Assessed (UKCA) Certificates removing all post-market restrictions
- ✓ Milestone highlights the device's robust safety profile, reduces regulatory burdens, and streamlines market Access
- ✓ Opportunity to re-submit marketing authorization application to Therapeutic Goods Administration (TGA)

Ongoing Clinical Trials

TRIPP-FFX

An open-label, multi-centre, randomized study of TaRgeted Intratumoural Placement of Phosphorous-32 (OncoSil™) in addition to FOLFIRINOX chemotherapy versus FOLFIRINOX chemotherapy alone in patients with unresectable locally advanced pancreatic adenocarcinoma

Objective

To assess the safety and efficacy of OncoSil™ when given in addition to standard FOLFIRINOX chemotherapy for treatment of Locally Advanced Pancreatic Cancer – opportunity to provide **label expansion** into standard of care chemotherapy

Study Sites

19 sites in Spain, UK, Belgium, Australia and Italy with:

- 15 sites open for recruitment
- **62/80** subjects recruited (78%)

Primary Endpoint

Safety and Tolerability as determined by the Adverse Event profile

Local Disease Control Rate at 16 weeks

PANCOSIL

Safety and feasibility of CT-guided percutaneous radionuclide therapy with the OncoSil™ device in patients with non-progressive locally advanced pancreatic cancer (PANCOSIL): an open-label, single-arm phase 1-2 feasibility study

Objective

To assess the safety and feasibility of **percutaneous CT-or ultrasound-guided RNT** using the OncoSil™ device in patients with non-progressive LAPC after induction chemotherapy treatment.

Study Sites

Amsterdam UMC & Antonius Hospital Nieuwegein

- 1/2 sites initiated
- **16/20** subjects recruited (80%)

Primary Endpoint

Safety and feasibility of percutaneous RNT using the OncoSil™ device defined by the percentage of device or procedure related CTCAE grade 3 or higher adverse events, until 90 days post-procedure

Summary

G-BA approval enables fully funded, revenue positive CED trial

Next steps: CRO tender and clinical trial protocol design (G-BA timeline)

Authorisation by the German Institute for the Hospital Remuneration System underscores growing recognition of OncoSil™ device in German healthcare system

Medical Device Regulation (**MDR) EU certification** from BSI

Next steps: Prepare for resubmission of application to TGA by Q2

TRIPP-FFX (78% recruited) and **PANCOSIL** (80% recruited)

Next steps: anticipated full recruitment end Q2 TRIPP-FFX, PANCOSIL end Q1

Note: dates are presented in calendar year

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