OncoSil Limited (ASX:OSL)

Developing pancreatic cancer treatment

Investor presentation – March 2024

Nigel Lange – CEO & Managing Director

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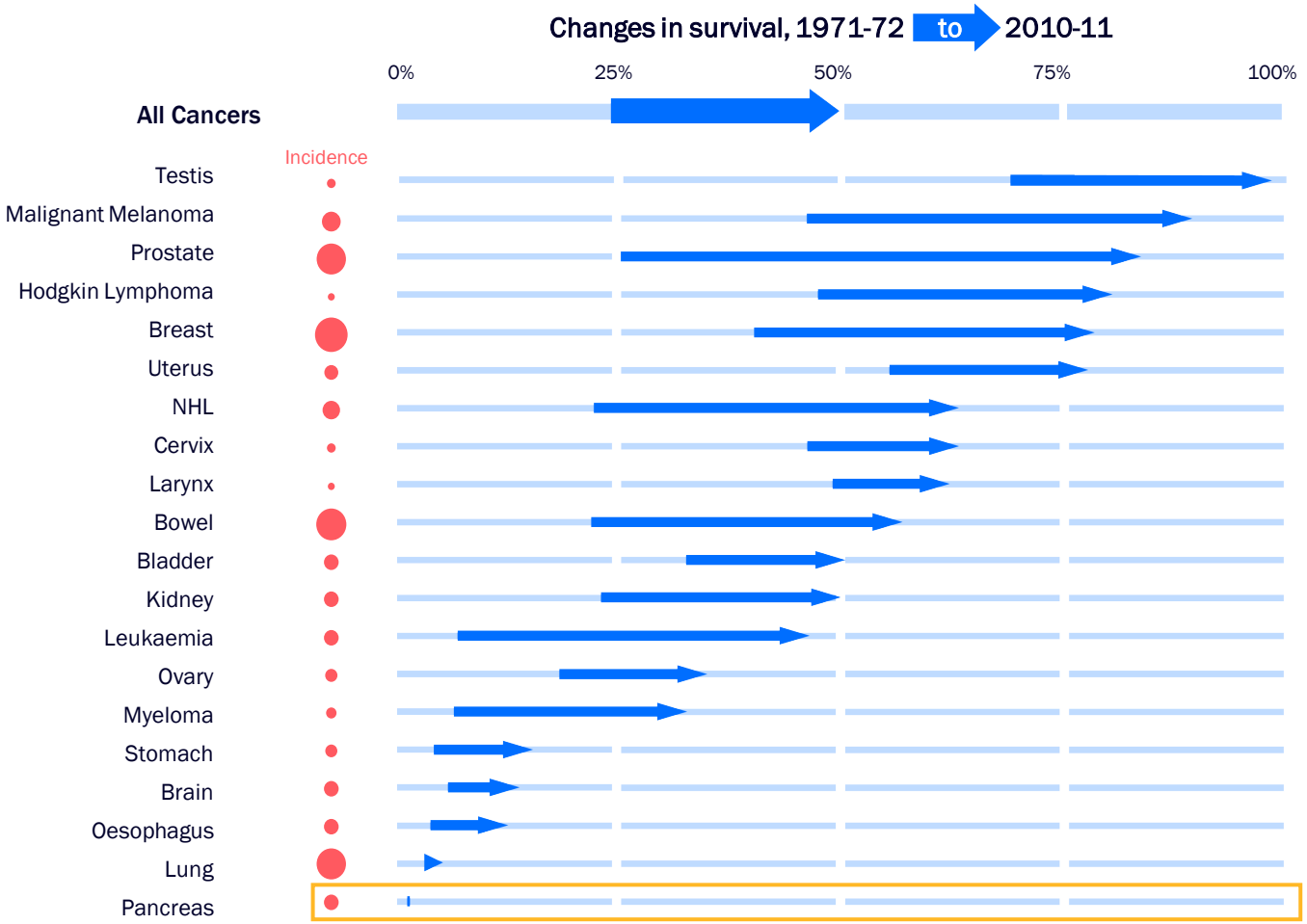
The information contained in this presentation is current as at 08 March 2024.

OncoSil: Improving outcomes for people with pancreatic cancer

OncoSil™ is a single-use brachytherapy device used to deliver a pre-determined dose of beta radiation directly into cancerous tissue. It is used in combination with chemotherapy.

An enhanced pancreatic cancer treatment finally at hand



- The prognosis for pancreatic cancer patients has remained almost unchanged for over 40 years[1]
- The reported five-year survival rate for the disease of 10%[2]

1. Cancer Research UK. www.cancerresearchuk.org/health-professional/cancer-statistics/survival/common-cancers-compared#heading-Three (accessed November 2021)
2. American Cancer Society. Cancer Facts & Figures 2021. https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2021/cancer-facts-and-figures-2021.pdf

OncoSil™ device revolutionises treatment of pancreatic cancer

- **The OncoSil™ device:** A commercial-stage breakthrough device delivering targeted radiotherapy for locally advanced pancreatic cancer
- **OncoSil™ device validation process well underway:**
  - ✓ Breakthrough designation received in the EU/UK and the US
  - ✓ Trial results are now validating the effectiveness of OncoSil™ device[1]
  - ✓ Patient onboarding in studies ongoing (adds to randomised data set)
- **Commercial treatments are now occurring:** With the OncoSil™ device approved for sale in 34 countries, its hospital footprint is steadily rising
- **A large global addressable market:** The number of patients diagnosed globally with pancreatic cancer is approximately 510K per annum[2] The target patient population for the current indication is
- **An experienced leadership team:** OncoSil's board and management are actively pursuing market access and sales opportunities

1. Ross PJ, Wasan HS, Croagh D et al. Results of a Single-Arm Pilot Study of 32P Microparticles in Unresectable Locally Advanced Pancreatic Adenocarcinoma with Gemcitabine/Nab-Paclitaxel or FOLFIRINOX Chemotherapy. ESMO Open February 2022; 7 (1): 100356. https://www.esmoopen.com/article/S2059-7029(21)00318-5/fulltext
2. Globocan 2022 Data, https://gco.iarc.who.int/today, accessed [18 March 2024]

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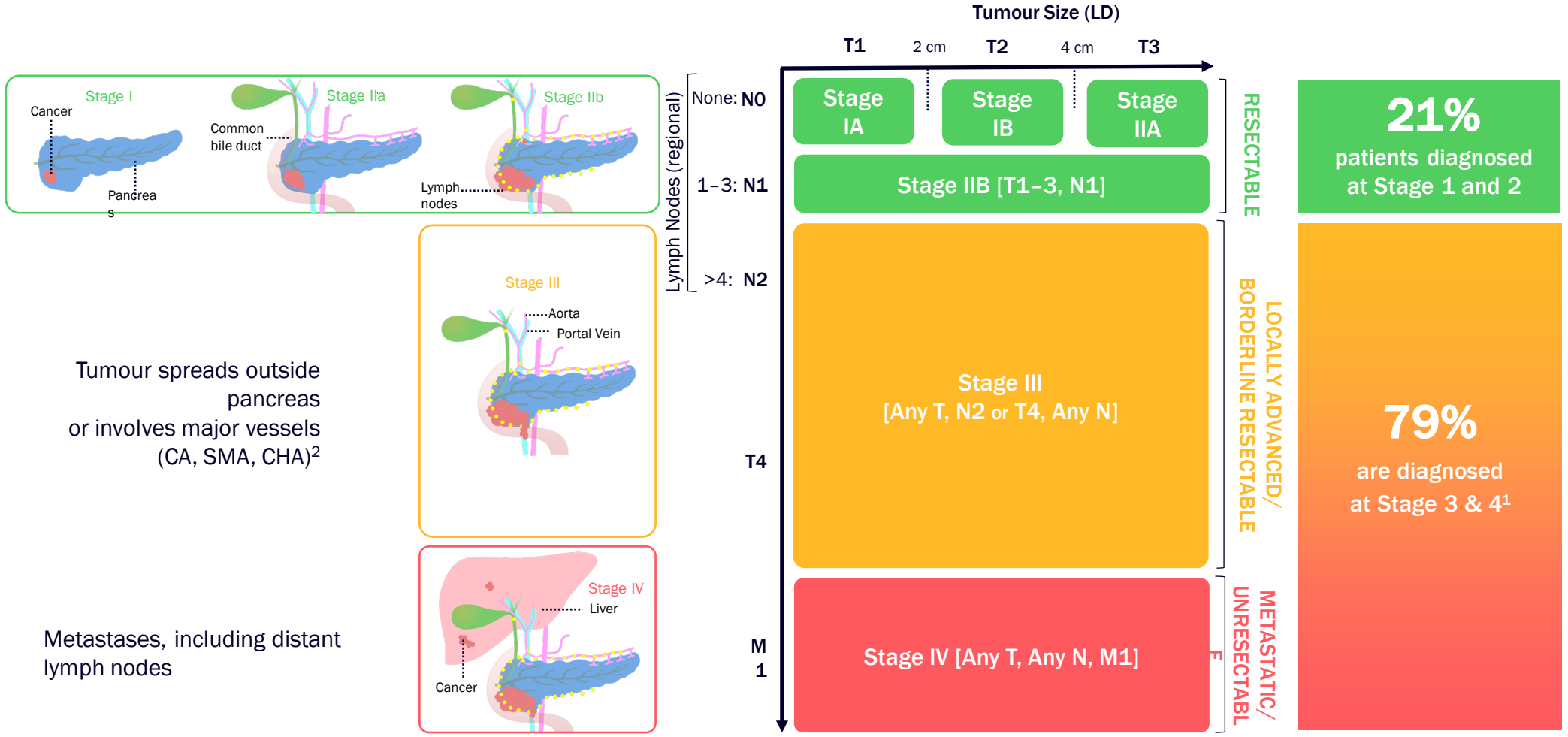
A primer on pancreatic cancer

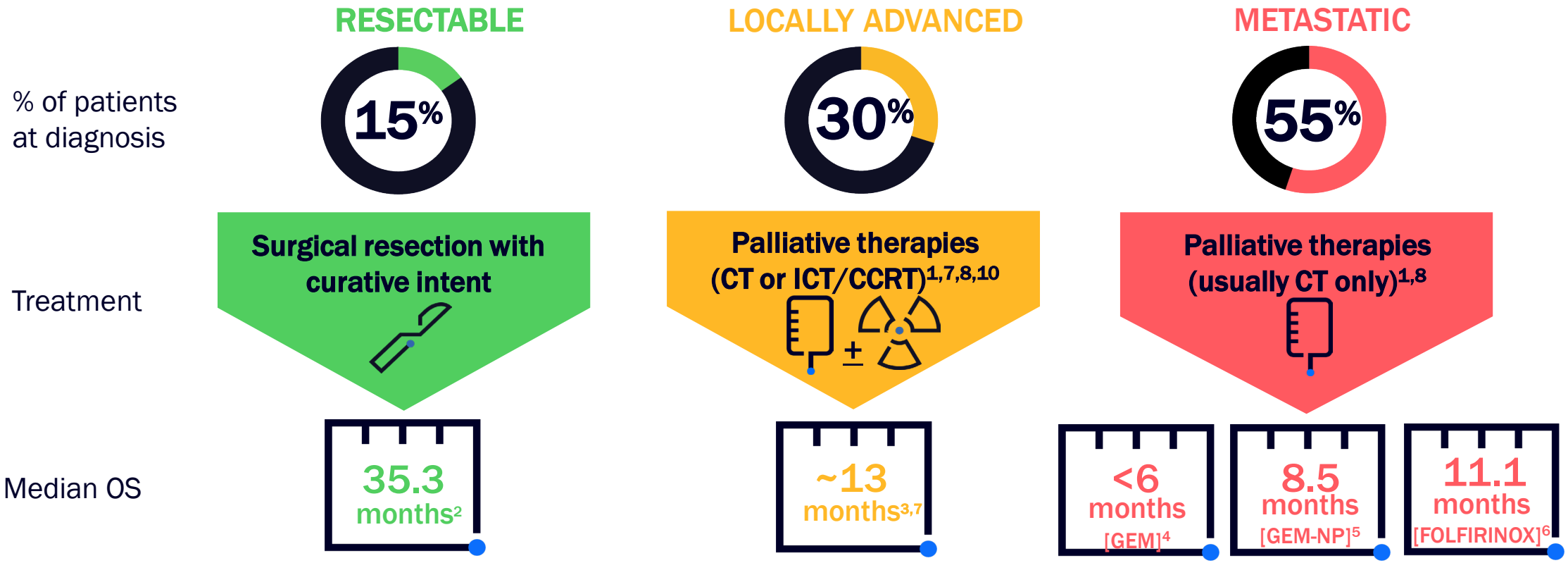
Clinical Stages of Pancreatic Cancer[1]



1. Image adapted from letswin.pc.org; AJCC, American Joint Committee on Cancer. Cancer Staging Manual, 8th Edition. Editors: Amin MB, Edge SB, Greene FL et al. 2018. Springer. (https://www.macmillan.org.uk/cancer-information-and-support/pancreatic-cancer/staging-and-grading-of-pancreatic-cancer (accessed November 2021)
2. CA - Celiac artery; CHA - Common hepatic artery; SMA - Superior mesenteric artery

Surgical Resection

The only potentially curative treatment for pancreatic cancer[1]



30% of LAPC patients shows metastatic progression with 3-6 months[9,10]

1. Ducreux M et al. Ann Oncol 2015; 26 (Suppl 5): v56–68.
2. Gemenetzis G et al. Ann Surg 2019; 270: 340–347.
3. Chang JS et al. Cancer Res Treat 2018; 50: 562–574 (suppl data).
4. Burris HA 3rd et al. J Clin Oncol 1997; 15: 2403–2413.
5. Von Hoff DD et al. N Engl J Med 2013; 369: 1691–1703.
6. Conroy T et al. N Engl J Med 2011; 364: 1817–1825.
7. Balaban EP et al. J Clin Oncol 2016; 34: 2654–2668.
8. National Comprehensive Cancer Network (NCCN) Clinical Practive Guidelines in Oncology: Pancreatic adenocarcinoma. Version 1.2020.
9, Huguet et al. J Clin Oncol 2010.
9. Mukherjee et al, Lancet Oncol 2013.
10. CT – Chemotherapy; ICT - Induction chemotherapy; CCRT - Concurrent chemoradiation therapy

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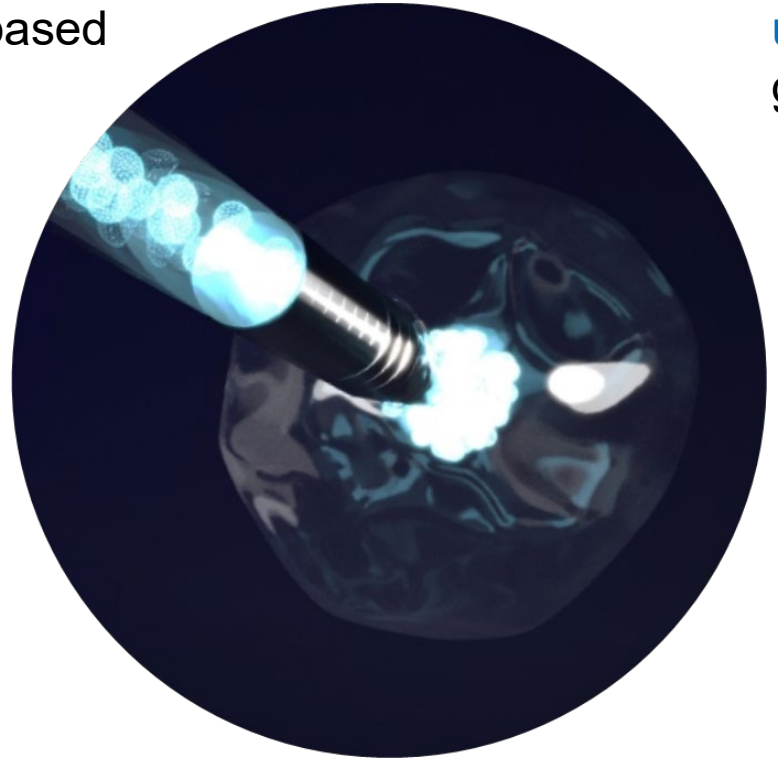
The OncoSil™ device

OncoSil™ Device

OncoSil™ is intended for the treatment of **locally advanced unresectable pancreatic cancer,** in combination with gemcitabine-based chemotherapy

OncoSil™ is implanted directly into a pancreatic tumour via injection under **endoscopic ultrasound** guidance



OncoSil™ is a **single-use** brachytherapy device comprised of microparticles and a diluent

98% of all radiation is delivered within **81** days of injection …

… causing damage to cancer cell DNA and **killing malignant cancer cell** and **no damage to surrounding tissue**

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FY 2024

Achievements FY2024

- Commencement of PancoSil trial – 1st patient treated
- TRIPP study now up to 12 sites with 17 patients included
- Innovation Funding (NUB) approval for 84 German hospitals
- Revised HDE dossier completed – currently under final review prior to FDA submission
- Commencement of 2nd manufacturing facility in Macquarie Park, Sydney
- EU MDR submission revisions completed, can be used for revised TGA filing upon approval
- New distributor agreement in Turkey completed (Saudi Arabia, South Korea in final stages of negotiation)

1. HDE - Humanitarian Device Exemption
2. FDA - Food and Drug Administration
3. DCC - Distal cholangiocarcinoma (or bile duct cancer)

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Validating OncoSil™ device's effectiveness

PanCO study demonstrated positive safety and efficacy signals

Of the many encouraging outcomes from the PanCO study[1], four are particularly important:

Established safety profile:
No evidence suggesting any additional risk from using OncoSil™

90.5% of OncoSil™ treated patients had **local disease control at 16 weeks**, which was the primary efficacy measure of the study and was statistically significant compared to the pre-set hypothesis

Although all study participants were initially unresectable, **1 in 3 patients (33%)** became **eligible for resection** after receiving OncoSil™, and nearly **1 in 4 patients (23.8%) underwent surgical resection with curative intent**

There was a **statistically significant reduction** in tumour volume for patients who received OncoSil™, with **57% of participants** having their tumour volume reduced by at **least 50%**

1. Ross PJ, Wasan HS, Croagh D et al. Results of a Single-Arm Pilot Study of 32P Microparticles in Unresectable Locally Advanced Pancreatic Adenocarcinoma with Gemcitabine/Nab-Paclitaxel or FOLFIRINOX Chemotherapy. ESMO Open February 2022; 7 (1): 100356. https://www.esmoopen.com/article/S2059-7029(21)00318-5/fulltext

PanCO results showing compelling evidence of downstaging

OncoSil™ converted patients with unresectable locally advanced pancreatic cancer (LAPC) to surgically resectable, transforming their prognosis and substantially extending survival

Why is resection important?

Surgical resection remains the only potentially curative treatment for pancreatic cancer, but is limited to ~15% of patients

Patients with LAPC are inoperable due to the size of the tumour and its proximity to major blood vessels

Chemotherapy helps to convert ~7% with unresectable LAPC to surgical resection[1]

What did the PanCO study show?

Adding OncoSil™ to chemotherapy led to a high proportion of patients having substantial reductions in their tumour volume (range +11% to -90%), with 57% having a >50% reduction[2]

1 in 3 patients with unresectable LAPC receiving OncoSil™ plus chemotherapy became eligible for curative surgery[2]

Nearly 1 in 4 patients (23.8%) with unresectable LAPC receiving OncoSil™ plus chemotherapy underwent surgery with curative intent[2]

At the end of the PanCO Study with a follow-up of 32 months, 6 of the 10 resected patients remained alive, 5 without any evidence of disease (26.4–35.3 months from enrolment in the study)[2,3]

1. Allerdice S et al. Naïve indirect treatment comparison of PanCO, a pilot study of OncoSil P-32 microparticles combined with gemcitabine + nab-paclitaxel or FOLFIRINOX chemotherapy, versus standard-of-care treatment in unresectable locally advanced pancreatic cancer. Presented at the World Congress of GI Cancer, Annals of Oncology 2020: 31 (Suppl 3); Abstract P-260.
2. Ross PJ et al. Results of a single-arm pilot study of 32P microparticles in unresectable locally advanced pancreatic adenocarcinoma with gemcitabine/ nab-paclitaxel or FOLFIRINOX chemotherapy. ESMO Open February 2022; 7 (1): 100356.
3. Data on file. OncoSil Medical Ltd.

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

Location

16-8 sites in Spain, UK, Belgium, Australia and Italy with:

- 12 sites open for recruitment
- 17 subjects recruited to date

Primary Endpoint

Safety and Tolerability as determined by the Adverse Event profile

Local Disease Control Rate at 16 weeks

PANCOSIL (Investigator Initiated Study)

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. Successful completion enables OncoSil to **expand the user base to include Interventional Radiology**

Study Sites

Amsterdam UMC & Antonius Hospital Nieuwegein
1/2 sites initiated
1/20 subjects recruited

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

Amsterdam UMC
Universitair Medische Centra

DPCG
Dutch Pancreatic Cancer Group

Innovation Funding (NUB) in Germany

Funding for the use of the OncoSil™ device in Europe's largest market

- German Institute for the Hospital Remuneration System (InEK) has authorized 84 German hospitals to negotiate funding for the OncoSil™ device classification under the innovation funding (NUB) program with the statutory health insurance (SHI) companies.
- OncoSil was granted a "Positive Status 1" classification under the innovation funding (NUB) program in 2021.
- In 2021, 25 hospitals submitted a request for NUB for the OncoSil™ device.
- By early calendar 2024, the latter number had more than tripled.
- Awaiting confirmation of study approval. Negotiations for funding can only begin under the NUB until the G-BA announce confirmation

G-BA Fully Funded trial in Germany

Fully-funded trial leading to public insurance reimbursement

In March 2022, the Federal Joint Committee (G-BA) recommended a fully-funded trial take place in Germany

Mar 2022

Favourable results from the clinical trial will lead to the OncoSil™ device being fully-funded for patients in Germany through public insurance reimbursement

OncoSil will receive revenue payments for the provision of the OncoSil™ device used within the clinical trial

The 36 leading university sites in Germany who had submitted NUB requests will also be able to participate within the clinical trial

The second round of stakeholder meetings was completed in September 2023. These meetings allows the GBA to gather further information for decision-making of the final coverage with evidence development (CED) study directive.

OncoSil MEDICAL

Corporate overview and leadership team

Corporate Overview

OncoSil Medical Limited | as at 19 March 2024[1]	
GICS:	Health Care – Pharmaceuticals, Biotechnology & Life Sciences (Life Sciences Tools & Services)
ASX Code:	OSL
ASX Listing Date:	15 August 2005
Market cap:	$17.8m
Shares on Issue:	1,974.5m
Share price:	$0.008
52-week high:	$0.033
52-week low;	$0.006
Average volume:	1,478,108
Free float	75.1%
Cash on Hand (December 2023 quarter)	$4.9m

Major Shareholders (% of listed shares, as at 19 March 2024)	
MRS SARAH CAMERON	11.99%
MR PETER ANDREW PROKSA	4.14%
BANNABY INVESTMENTS PTY LTD	3.53%

1. OSL share market data and share price chart sourced from: https://www.asx.com.au/markets/company/OSL

Leadership team

Nigel Lange

Managing Director & CEO

30+ years experience in medical device industry

Served as Group COO and Interim Group CEO of Sirtex Medical

Douglas Cubbin

Non-executive Chairman

Experienced biopharmaceutical executive with over 30 years' experience in senior roles across varied industries.

Was a key member of Telix Pharmaceuticals (ASX:TLX) which completed IPO, raised $270m in capital.

Gabriel Liberatore

Non-executive Director

Dr Liberatore is an experienced biopharmaceutical executive with over 25 years' experience. Until recently, he was the Group Chief Operating Officer at Telix Pharmaceuticals (ASX:TLX)

Leadership team

David Turner
Head of Medical Affairs

40+ years experience in pharmaceutical, medical device and health technology industries

Henk Tissing
Director of Clinical Development

25+ years industry experience in oncology with pharmaceuticals and medical devices. Senior clinical development

roles at Sirtex Medical, BTG, A-Z and Sanofi Aventis

Christian Dal Cin
Chief Financial Officer

Christian has over 20 years' experience with listed and private companies includes corporate secretarial, accounting and general management through The CFO Solution and previous roles.

Renzo DiCarlo
Head of Transformation

A proven nuclear medicine executive Renzo brings over 25 years' experience in therapeutic drugs and medical devices.

Dr Jon Bell
Chief Medical Officer

8+ years experience as an interventional radiologist and an internationally recognised expert in interventional oncology

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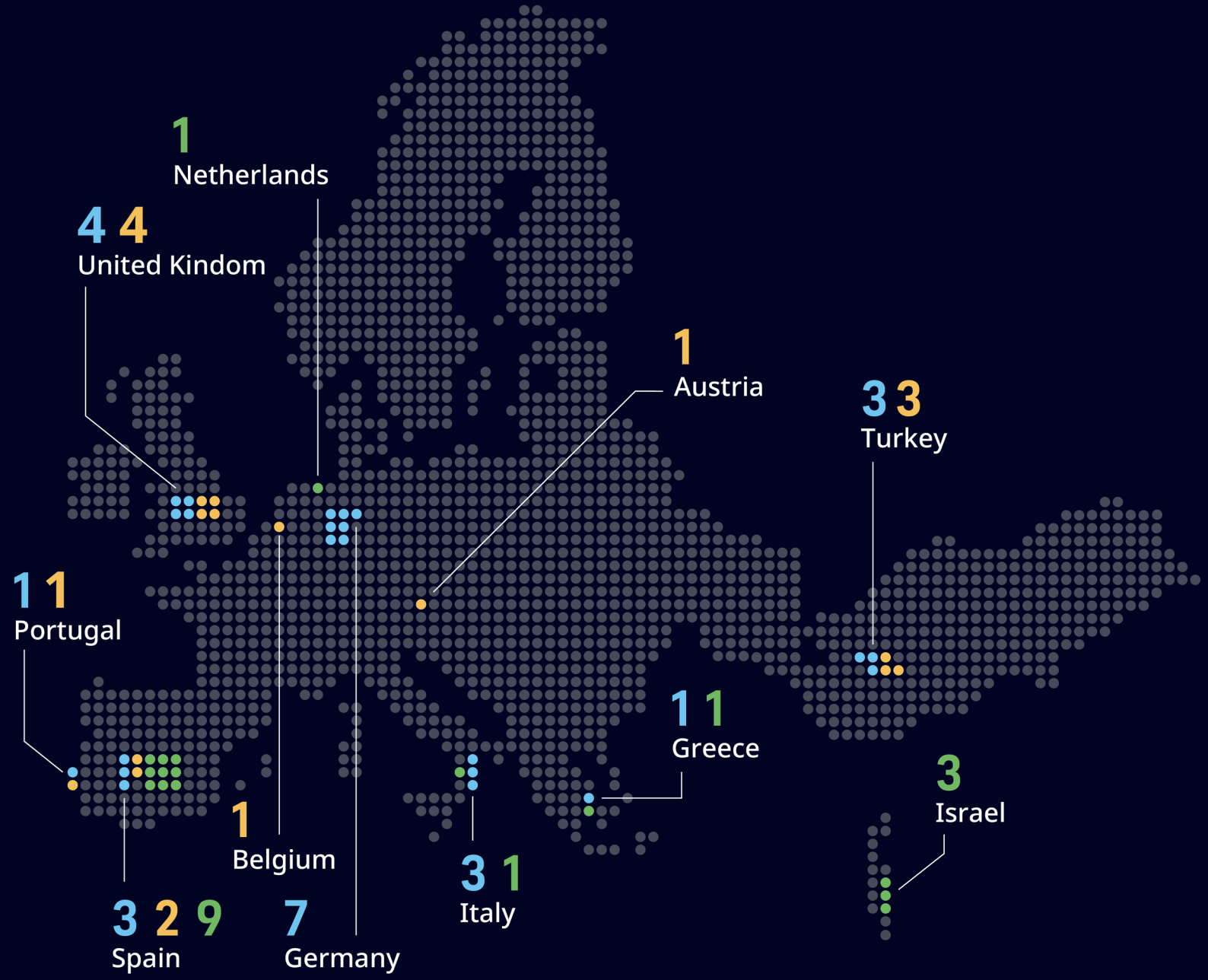
Commercialisation strategy & investment thesis

Targeted commercialisation strategy deliverables

- G-BA progressed to commercial agreement
- FDA processes advanced
- Re-engage TGA for approval in Australia
- A steady uplift in the number of commercial treatments utilising OncoSil™ device
- Additional distribution agreements underway in several markets such as South Korea, Saudi Arabia and UAE
- A broadening and deepening of our geographic footprint

Sites undertaking OncoSil™ Device treatments continue to grow



- Training Commenced
- Training Completed and ready to start
- Sites using OncoSil

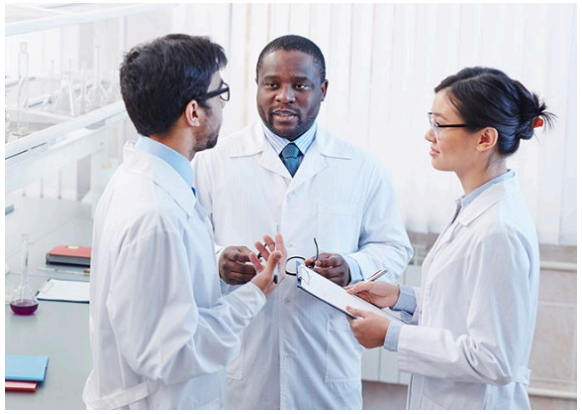
OncoSil's investment thesis

Development of OncoSil™ device

A unique medical technology

Validation process continues, but is now well-advanced

Much of the capex spend on the device's development is complete



Early commercialisation now occurring

Hospitals utilising the OncoSil device continue to rise

The device is currently approved for sale in 34 countries

Some of these hospital treatments are already revenue generating

Regulatory approvals now work-in-progress

Green light on G-BA funding front could be a game changer

Continued advancement of HDE approval in US

Pursuit of TGA application in Australia

The Oncosil™ device is now in early-stage commercialisation

The OncoSil™ device, an effective treatment for locally advanced pancreatic cancer, is now penetrating its already large and continually growing target addressable markets

- ✓ Many key components of commercialisation strategy are already in place (breakthrough device designation; market approvals in a steadily increasing number of countries/regions)
- ✓ The device is approved for sale in 34 countries
- ✓ A growing network of hospitals located across an expanding geographic footprint are treating patients with the OncoSil™ device
- ✓ OncoSil™ has converted patients with unresectable locally advanced pancreatic cancer to surgically resectable, transforming their prognosis and substantially extending survival[1]
- ✓ Working towards innovation funding in Germany
- ✓ Further studies are now being progressed
- ✓ OncoSil's journey to commercialisation is being led by a highly experienced Board and Senior Executive team
- ✓ Market access and clinical development teams are working on multiple activities to expand the addressable market

1. Ross PJ, Wasan HS, Croagh D et al. Results of a Single-Arm Pilot Study of 32P Microparticles in Unresectable Locally Advanced Pancreatic Adenocarcinoma with Gemcitabine/Nab-Paclitaxel or FOLFIRINOX Chemotherapy. ESMO Open February 2022; 7 (1): 100356. https://www.esmoopen.com/article/S2059-7029(21)00318-5/fulltext

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Developing pancreatic cancer treatment

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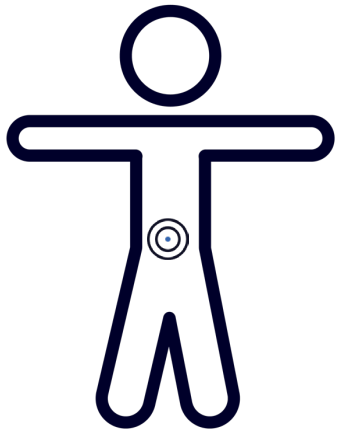
Appendices

Optimal treatments of pancreatic cancer

Local

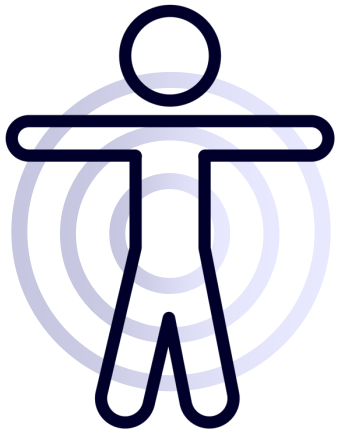


Surgery ± Radiation

Optimal Treatment Outcomes

Two Targets

Systemic



Chemotherapy ± Radiation

How the OncoSil™ device works