OncoSil MEDICAL

Investor Webinar

FDA Approval: A New Chapter for OncoSil™

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Targeted Approach • Positive Impact

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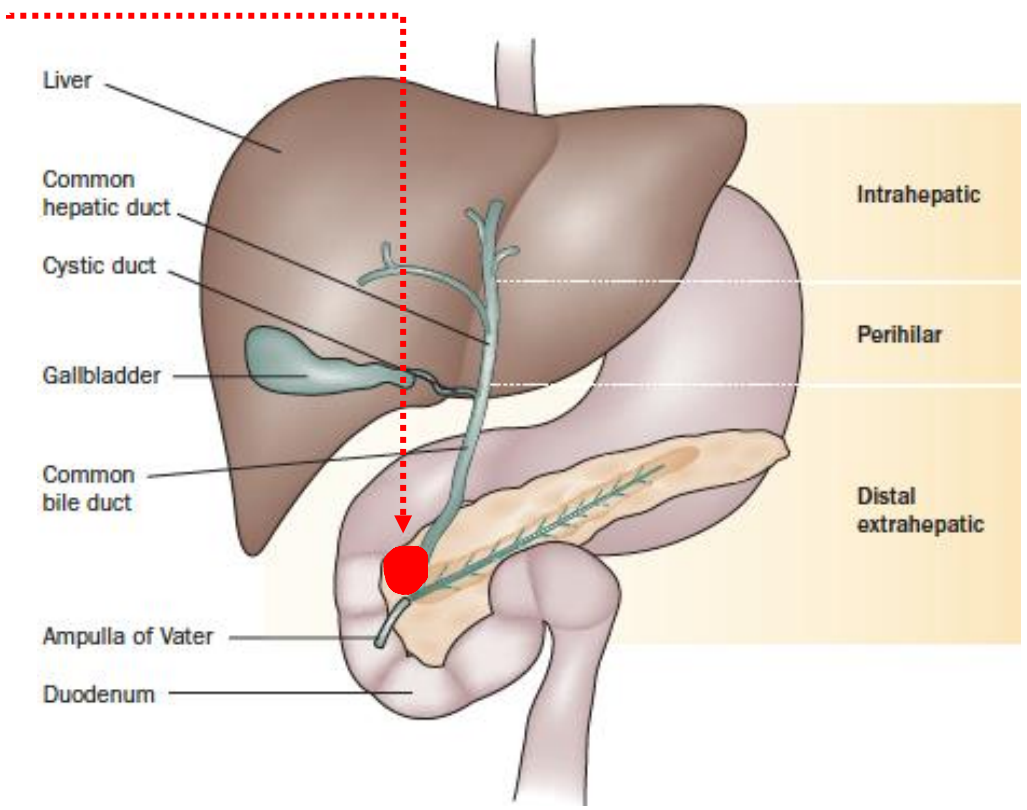
OncoSil™ Device Receives U.S. Humanitarian Device Exemption Approval from FDA for Distal Cholangiocarcinoma

- U.S. Food and Drug Administration (FDA) has granted Humanitarian Device Exemption (HDE) approval for the OncoSil™ device for the treatment of distal cholangiocarcinoma (dCCA) in the United States.
- FDA approval completes OncoSil Medical's HDE regulatory process and provides U.S. marketing authorisation for the approved indication, enabling commercial marketing and sale subject to HDE requirements and conditions.
- OncoSil™ device the first and only U.S. FDA approved Class III device for the treatment of dCCA.
- OncoSil Medical will now commence a focused U.S. commercialisation strategy targeting leading academic cancer centres and specialist hepatobiliary oncology teams, with U.S. launch expected in the second half of FY27.

Distal Cholangiocarcinoma (dCCA)

Patients with dCCA have a poor prognosis with limited treatment options and survival

- dCCA develops as a cancerous tumour in the common bile duct within the head of the pancreas.
- Clinical symptoms of the disease are not evident until the tumour has developed to a point that it is difficult to remove with surgery.
- More than 50% of patients who develop dCCA cannot have the tumour removed surgically (the tumour is “unresectable”).[1]
- Unresected, non-metastatic dCCA is associated with a poor prognosis, with reported median overall survival of just 6.7 months,[2] while dCCA incidence has been reported to be increasing by 1.4% annually.[3]
- Treatments for unresectable tumours involve the placement of a stent, chemotherapy, external radiation therapy, or a combination of the two.
- Side effects due to chemotherapy and radiotherapy are considerable and have a negative impact on the quality of life for the patient.
- OncoSil™ has shown promise for dCCA [3] and is the basis for the HDE.
- The advantage of OncoSil™ is the ability to deliver a high radiation dose to the target dCCA tumour with minimal side-effects.



References:

1. Hester CA, Dogeas E, Augustine MM, et al. Incidence and comparative outcomes of periampullary cancer: A population-based analysis demonstrating improved outcomes and increased use of adjuvant therapy from 2004 to 2012. J Surg Oncol 2019; 119:303-317. doi: 10.1002/jso.25336
2. Strijker, M. et al. (2019) ‘Treatment and survival of resected and unresected distal cholangiocarcinoma: a nationwide study’, Acta Oncologica, 58(7), pp. 1048–1055.
3. Rahman R, et al. (2022). “Age trends in biliary tract cancer incidence by anatomical subtype: A Swedish cohort study.” European Journal of Cancer, 175, 291–2982.
4. Ross PJ et al. Results of a single-arm pilot study of ^{32}P microparticles in unresectable locally advanced pancreatic adenocarcinoma with gemcitabine/nab-paclitaxel or FOLFIRINOX chemotherapy. *ESMO Open* February 2022; 7 (1): 100356.

Treatment for Unresectable dCCA and Impact on Quality of Life (QoL)

The dCCA disease course has a negative impact on QoL for the patient

- Since most dCCA patients have a stent implanted, the challenge for clinicians is to maintain the patency of the common bile duct.
- Invariably the stent occludes within 4–6 months due to tumour development .
- This results in significant complications including extreme abdominal pain and cholangitis (inflammation and infection) which necessitates admission to hospital:
  - interruption of chemotherapy
  - possible surgery to replace the stent and reopen the bile duct
  - administration of antibiotics to control the infection
- As the disease continues to progress, subsequent re-occlusion of the stent results in repeated admissions to hospital.
- The patient inevitably succumbs to sepsis (systemic infection) and liver or multi-organ failure.

*OncoSil™ has the potential to **control local tumour development** and **maintain bile duct patency**, resulting in **increased quality of life** and **extended survival**.*

HDE: Accelerating US Market Access for OncoSil™ in dCCA

What is HDE Pathway?

- Designed for medical devices targeting rare diseases affecting **fewer than 8,000 individuals** annually
- Permits approval based on demonstration of **probable benefit outweighing risk**, rather than requiring the extensive clinical evidence of a costly Phase III randomised clinical trial needed for a (Pre-market approval) PMA
- Provides **shortened market access with a cost-efficient** route

Why HDE is Relevant for OncoSil™ in dCCA

- dCCA is a rare and highly aggressive cancer with limited treatment options and poor prognosis
- OncoSil™ is being positioned as a **novel, localised radiation treatment that can address a significant unmet need** in this patient population
- Under this approval, OncoSil Medical will be authorised to **commercially market and sell** the OncoSil™ device in the US*

Strategic Benefit for OncoSil

- ✓ **Reduced** clinical development **burden and cost (no randomised trial)**
- ✓ **Earlier US commercial entry** opportunity
- ✓ **Homogeneous reimbursement landscape**
- ✓ **Shorter regulatory timeline** versus PMA
- ✓ Ability to generate **real-world evidence** and physician adoption post-approval
- ✓ Establishes US market presence in a high-value oncology indication

HDE Eligibility → FDA Approval → Coding & Reimbursement → Initial Commercialisation → US Adoption

* Subject to oversight conditions standard under the HDE framework

U.S. dCCA Patient Population Represents an A$80m Annual Addressable Market

Annual U.S. cholangiocarcinoma cases	~ 8,000 [1]
dCCA (~30 - 40%)	~ 2,800 [2]
Unresected, non-metastatic dCCA (~33%)	~ 1,000 [3]
Assumed ASP per patient	US$55,000
Total Addressable Market (TAM)	~ A$80 million*

6.7 MONTHS
Median overall survival unresected, non-metastatic dCCA[3]

+1.4% P.A.
Reported annual increase in dCCA incidence[4]

1. American Cancer Society / Key Statistics for Bile Duct Cancer / https://www.cancer.org/cancer/types/bile-duct-cancer/about/key-statistics.html Last revised on October 11, 2024
2. Terasaki F, Sugiura T, Okamura Y, et al. Systemic immune-inflammation index as a prognostic marker for distal cholangiocarcinoma. Surg Today. 2021;51(10):1602–1609. doi:10.1007/s00595-021-02312-7
3. Includes incidence increases of 1.4% per annum. Strijker, M. et al. (2019) 'Treatment and survival of resected and unresected distal cholangiocarcinoma: a nationwide study', Acta Oncologica, 58(7), pp. 1048–1055
4. Rahman R, et al. (2022). "Age trends in biliary tract cancer incidence by anatomical subtype: A Swedish cohort study." European Journal of Cancer, 175, 291–2982

* USD/AUD = 1.43

HDE Approval Opens a New Treatment Option for Patients in U.S. with dCCA

The FDA has approved the OncoSil™ device under the HDE pathway for the following indication:

- OncoSil™ is intended for intratumoral implantation into a solid tumour via injection under endoscopic ultrasound guidance.
- OncoSil™ is indicated for the treatment of patients with distal cholangiocarcinoma (dCCA) that is both unresectable (locally advanced and/or unfit for surgery) and non-metastatic, as an adjunct to systemic therapy.
- OncoSil™ is indicated for the treatment of patients over 21 years of age.
- Implantable components of OncoSil™ are supplied sterile and are intended for single-patient, single-use.

Distal Cholangiocarcinoma Study

Post-Approval Study (PAS)

STUDY DESIGN

Multicentre | Observational | Prospective

5	30	24 MONTHS
SITES	PATIENTS	FOLLOW UP

STUDY OBJECTIVE

Evaluate the safety and probable benefit of OncoSil™ in patients with distal cholangiocarcinoma (dCCA) that is both unresectable (locally advanced and/or unfit for surgery) and non-metastatic, as an adjunct to systemic therapy.

OUTCOMES ASSESSED

- Overall survival
- Safety and tolerability
- Implantation performance
- Biliary patency
- Local disease control/progression
- Target tumour response
- Progression-free survival
- Local progression-free survival
- Surgical resection rates and outcomes

Initial ~US$1.7 million in commercial revenue for OncoSil Medical

Focused U.S. Commercialisation Strategy and Market Launch

Pathway to a targeted U.S. launch of the OncoSil™ device in 2H FY27

Activate Priority Treatment Centres

- Focus launch on leading academic cancer centres with established **dCCA and hepatobiliary oncology expertise**
- Establish and activate priority treatment sites ahead of the planned **U.S. launch in 2H FY27**
- Build a **concentrated initial footprint**, supported by a small, **focused U.S. team**, designed to support high-quality execution and early adoption
- Low capital requirements under initial commercial model

Build Clinical Advocacy and Launch Readiness

- **Engage key opinion leaders and multidisciplinary clinical teams** to support clinical adoption
- **Enhance clinician education and training** so treatment teams are prepared and supported from launch
- Leverage early centre experience to **build confidence, advocacy and referral momentum**

Enable Access and Drive Adoption

- **Submit the application for Transitional Pass-Through Payment Status in Q1 FY26** and advance market-access pathways to facilitate patient access to treatment
- Deploy **targeted physician, patient and referral initiatives** to build awareness and support patient identification
- Drive adoption through **coordinated market access, education and focused commercial execution**

Commercial objective: establish a high-quality early U.S. centre network, remove access barriers and create a scalable platform for broader adoption.

Summary

FDA HDE Approval Granted

- On 14 August 2026 (U.S. Eastern Time), the FDA has granted Humanitarian Device Exemption (HDE) approval for the OncoSil™ device for the treatment of distal cholangiocarcinoma (dCCA) in the United States.
- Approval completes the Company's HDE regulatory process and provides U.S. marketing authorisation for the approved indication.

Commercial Authorisation & Market Opportunity

- OncoSil Medical is authorised to commercially market and sell the OncoSil™ device in the U.S. for the approved indication, subject to applicable HDE requirements and conditions.
- FDA approval provides entry into the world's largest healthcare market, representing an estimated A$80 million annual Total Addressable Market (TAM) and significantly broadens the commercial opportunity for the OncoSil™ platform.

U.S. Commercialisation

- The Company will commence a focused U.S. commercialisation strategy targeting leading academic cancer centres and specialist hepatobiliary oncology teams.
- OncoSil™ is expected to launch in the U.S. during the second half of FY27.

Outlook

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Upcoming Milestones in FY27

1H FY27

- OncoSil™ device US label filing to FDA (HDE)
- Presentation of TRIPP-FFX Clinical Trial Results at ESMO GI Congress
- Completion of validation of manufacturing at Cyclotek
- PALACROS European consortium | PULSE trial
- FDA HDE approval for distal cholangiocarcinoma (dCCA)
- ISO 13485 Certification OncoSil|Cyclotek manufacturing facility
- G-BA funded study commencement
- Transitional Pass Through Payment Application: Centers for Medicare and Medicaid Services (CMS) - Reimbursement
- EU regulatory submission – percutaneous label change (PANCOSIL)
- EU regulatory submission – FOLFIRINOX label change (TRIPP-FFX)
- Commercial sales from OncoSil|Cyclotek manufacturing facility in Sydney*

2H FY27

- EU regulatory approval – percutaneous label change (PANCOSIL)
- EU regulatory approval – FOLFIRINOX label change (TRIPP-FFX)
- Launch of OncoSil™ device in Australia
- Launch of OncoSil ™ device in the United States*

* Subject to approvals

Q&A

Learn more about OncoSil Medical:

- **Website**
- **ASX announcements**
- **LinkedIn**

This announcement was authorised by the Board of Directors of OncoSil Medical Limited.

INTENDED USE / INDICATIONS FOR USE: The OncoSil™ System is intended to induce prolonged local tumour control and tumour size reduction in patients with locally advanced unresectable pancreatic cancer, in addition to gemcitabine-based chemotherapy, by implantation of radioactive Phosphorous-32 Microparticles into pancreatic tumours under endoscopic ultrasound guidance. OncoSil™ is indicated for the treatment of patients with locally advanced unresectable pancreatic cancer, in addition to gemcitabine-based chemotherapy.

This information is intended for healthcare professionals only. All medical treatments carry benefits and risks. For safety related information, please refer to the OncoSil™ System Instructions for Use.

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