ASX Announcement

17 August 2026

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

Key Highlights

- **United States Food and Drug Administration (U.S. FDA) has granted Humanitarian Device Exemption (HDE) approval for the OncoSil™ device for the treatment of distal cholangiocarcinoma (dCCA) in the U.S.**
- **U.S. FDA approval represents the most significant regulatory milestone in OncoSil Medical's history, completing the Company's HDE regulatory process and providing U.S. marketing authorisation for the OncoSil™ device**
- **The OncoSil™ device is the first and only U.S. FDA-approved Class III device for the treatment of dCCA, a rare bile duct cancer with incidence growing at 1.40% per annum [1]**
- **Approval for unresectable, non-metastatic dCCA patients who have limited treatment options with median overall survival as little as 6.7 months [2]**
- **Annual U.S. addressable market of approximately 1,000 patients, representing a potential addressable market of approximately A$80 million per annum [3]**
- **OncoSil Medical will commence its focused U.S. commercialisation strategy, targeting leading academic cancer centres and specialist hepatobiliary oncology teams, with the Company expecting to launch OncoSil™ in the U.S. during the second half of FY27**

Investor webinar with Nigel Lange (CEO/MD) at 4.00 pm AEST today – details below

Sydney, Australia – 17 August 2026: OncoSil Medical Limited (ASX: OSL) ("OncoSil Medical" or "the Company"), a medical device company developing targeted radiation therapies for difficult-to-treat cancers, is pleased to announce that the 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.

The approval represents a significant milestone for OncoSil Medical, completing the Company's HDE regulatory process and providing U.S. marketing authorisation for OncoSil™ for this indication under the HDE framework. FDA approval represents a transformational step in OncoSil Medical's U.S. expansion, significantly broadening the commercial opportunity for the OncoSil™ platform and providing entry into the world's largest healthcare market.

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Nigel Lange, CEO & Managing Director of OncoSil Medical, said:

"FDA approval of the OncoSil™ device under the HDE pathway represents the most significant milestone in OncoSil Medical's history and a transformational moment for our Company. Most importantly, it provides a pathway making OncoSil™ available for patients with dCCA in the United States, where there remains significant unmet clinical need.

I would like to sincerely thank everyone who has contributed to this achievement over the years. This includes our clinical investigators and healthcare professionals, our regulatory and scientific partners, the patient advocacy and research groups, notably the Cholangiocarcinoma Foundation, our Board of Directors and shareholders, our employees, and above all the patients, and their families who have participated in and supported our clinical programs.

Our attention now turns to successfully launching OncoSil™ in the United States. We will work with leading cancer centres and clinical teams to establish treatment sites, advance reimbursement and market access, and build the foundations for sustainable adoption. This approval marks the beginning of an exciting new chapter for OncoSil Medical as we work to make a meaningful difference to patients facing this challenging cancer."

Dr Juan Valle, Chief Medical Officer at the Cholangiocarcinoma Foundation, said:

"Distal cholangiocarcinoma is a rare and aggressive cancer with a significant need for new therapeutic approaches. The FDA's HDE approval of this device is an important development, providing eligible U.S. patients and clinicians with an additional treatment option through targeted radiation delivered directly within the tumour. I welcome the opportunity for U.S. specialist centres to gain experience with OncoSil™ and further understand its role in the multidisciplinary treatment pathway for eligible patients with dCCA."

dCCA: A rare cancer with poor prognosis and limited treatment options

dCCA is a rare and aggressive cancer that develops in the distal common bile duct, in the head of the pancreas. The disease is often diagnosed at an advanced stage, as symptoms may not become apparent until the tumour has progressed to a point where surgical removal is difficult or no longer possible, with more than 50% of patients unable to undergo potentially curative resection.[4] Patients with unresectable, non-metastatic dCCA have a poor prognosis, with reported median overall survival of approximately 6.7 months,[2] while dCCA incidence has been reported to be increasing by approximately 1.4% annually.[1] Treatment options remain limited and typically include biliary stenting to maintain bile duct patency together with systemic therapy and, in selected patients, radiation therapy.

Disease progression can lead to recurrent biliary obstruction, stent occlusion, cholangitis and hospitalisation, potentially interrupting systemic treatment and requiring further interventions. These complications, together with the burden and side effects of treatment, can significantly impact patients' quality of life and highlight the need for additional treatment options that aimed at improving local tumour control and clinical outcomes.

Significant U.S. market opportunity with A$80 million annual total addressable market

Approximately 8,000 people diagnosed with cholangiocarcinoma in the United States each year.[5] dCCA is an anatomical subtype of cholangiocarcinoma and is estimated to account for approximately 30-40% of cholangiocarcinoma cases.[6] Within the dCCA population, a subset of patients will fall within the population covered by the FDA-approved indication for OncoSil™, which is limited to patients with dCCA that is both unresectable (locally advanced and/or unfit for surgery) and non-metastatic, as an adjunct to systemic therapy. This represents an estimated patient pool of approximately 1,000 per annum and A$80 million annual Total Addressable Market (TAM) for the OncoSil™ device in the United States.[3]

HDE pathway provides a regulatory route for rare diseases with significant unmet need

The FDA's HDE pathway provides a regulatory pathway for medical devices intended to treat or diagnose rare diseases or conditions affecting no more than 8,000 individuals in the United States annually. Unlike the traditional Premarket Approval (PMA) pathway, an HDE does not require demonstration of reasonable assurance of effectiveness; instead, the FDA must determine that the device does not pose an unreasonable or significant risk and that its probable benefit outweighs the risks of its use. The pathway is particularly relevant to the OncoSil™ device given the rarity of dCCA; the poor prognosis associated with unresectable disease and the limited treatment options currently available. HDE approval therefore provides OncoSil Medical with an opportunity to introduce the OncoSil™ device into the U.S. market for this high-unmet-need patient population.

FDA HDE approval establishes pathway to U.S. commercialisation

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.

As a condition of approval, use and distribution of the OncoSil™ device in the U.S. will initially be restricted to a maximum of five treatment centres, with appropriately trained practitioners, as part of an FDA-required Post-Approval Study (PAS). The PAS will be a multicentre, prospective study evaluating the safety and probable benefit of the OncoSil™ device in the approved patient population. The study is expected to enrol 30 patients, who will be followed for up to 24 months. The final study protocol and associated requirements for the PAS are expected to be confirmed with the FDA. The Company anticipates each patient enrolled under the PAS will receive a reimbursed treatment, representing US$1.7 million in revenue for OncoSil Medical.

OncoSil to commence U.S. commercialisation strategy and market launch

Following receipt of the HDE approval, OncoSil Medical will commence a focused U.S. commercialisation strategy centred on leading academic cancer centres with established expertise in dCCA and hepatobiliary oncology, with the Company expecting to launch the OncoSil™ device in the U.S. during the second half of FY27. Key activities will include establishing and activating priority treatment centres, engaging key opinion leaders and multidisciplinary clinical teams, and submitting an application for Transitional Pass-Through Payment Status in Q1 FY26 as part of advancing the necessary reimbursement and market-access pathways.

The Company will also enhance its clinician education and training programs to ensure treatment teams are well-prepared and supported from launch, alongside targeted marketing, physician, patient and referral initiatives to build awareness, support patient identification, facilitate access to treatment and drive adoption of the OncoSil™ device in the U.S.

Investor webinar

OncoSil Medical will be hosting an investor webinar at 4.00 pm AEST today, where the Company's CEO & Managing Director, Nigel Lange will discuss the significance of the FDA HDE approval and outline the next steps for the Company (separate ASX announcement today).

Click **here** to register for the webinar any time today through to the 4:00 pm start.

A recording of the webinar will be available on the Company's website following the event.

Click **here** to view this announcement on Investor Hub.

Authorisation & Additional Information

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

For further information, please contact:

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About OncoSil Medical

OncoSil Medical (ASX:OSL) is a global medical device company focused on Interventional Oncology. OncoSil Medical's mission is to improve the outcomes for people living with cancer by utilizing the selected and targeted intratumoural placement of Phosphorous-32 (^{32}P) Microparticles in addition to chemotherapy.

OncoSil Medical has developed OncoSil™ device for the treatment of unresectable locally advanced pancreatic cancer. Its targeted approach enables healthcare professionals to deliver a greater radiation dose directly into the tumour compared to external beam radiotherapy, while sparing surrounding critical organs.

Pancreatic cancer is the 12th most common cancer in men and the 11th most common cancer in women across the globe, with 500,000 new cases detected every year.[7] Since pancreatic cancer is generally diagnosed at a later stage, it has a poor prognosis for long-term

survival.

OncoSil™ has received CE Marking approval, providing marketing authorisation in both the EU and the UK. OncoSil™ is designated as a breakthrough device in both Europe and the United States. It is currently approved for sale in 30+ countries including European Union, United Kingdom, Australia, Türkiye, Saudi Arabia and Israel, with commercial treatments using the device already undertaken in Spain, Italy, Austria, Germany, Greece, Türkiye, Portugal, Israel and the UK.

To learn more, please visit: www.oncosil.com/

About HDE

Humanitarian Device Exemption (HDE) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

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1. 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
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. See accompanying Investor Presentation lodged to ASX today for further information. Assumes OncoSil™ selling price of US$55k and AUD/USD of 0.70
4. 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
5. 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
6. 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
7. https://gco.iarc.fr/en