ASX Announcement

9 June 2026

OncoSil Reaches Final FDA Review Stage for Humanitarian Device Exemption Application

Highlights

- U.S. Food and Drug Administration (FDA) confirms all outstanding questions relating to OncoSil's Humanitarian Device Exemption (HDE) application for the treatment of distal cholangiocarcinoma (dCCA) in the United States (U.S.) have been satisfactorily addressed.
- HDE application advances to the final FDA review stage prior to a potential approval decision, with only final device labelling and any post-market study updates requested.
- FDA advises it intends to complete its review within 45 days of OncoSil's final submission, which will occur within 30 days, and grant the HDE.

Investor webinar with Nigel Lange (CEO/MD) at 10.30 am AEST today – details below

Sydney, Australia – 9 June 2026: OncoSil Medical Limited (ASX: OSL) ("OncoSil Medical" or "the Company"), a medical device company focused on localised treatments for patients with unresectable locally advanced pancreatic cancer (LAPC), is pleased to announce that it has received formal communication from the FDA confirming that its HDE application for the OncoSil™ device for the treatment of dCCA in the U.S. has progressed to the final stage of the FDA review process prior to potential approval.

On 3 June 2026 (U.S. time), the FDA advised the Company that all previously raised questions related to the HDE application have been satisfactorily addressed. The FDA's correspondence represents a significant regulatory milestone, as it confirms completion of the substantive review process and moves the application to the final administrative stage before a decision on approval.

As part of this final step, the FDA has requested that OncoSil submit within 30 days:

- final labelling for the OncoSil™ device; and
- any modifications to the Company's proposed post-market study, if applicable.

The FDA further advised that, upon receipt of the requested information, it intends to complete its review within 45 days and grant the HDE.

This communication places OncoSil™ at the last regulatory step before potential HDE approval in the U.S., representing the most advanced stage reached by the Company's U.S. regulatory program to date.

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

"The FDA's confirmation that all outstanding questions have been resolved is a major achievement for the Company and an important validation of the extensive work undertaken throughout the HDE review process. Importantly, the FDA has now moved the application to the final stage before potential approval and has requested only the submission of final labelling and any updates to our proposed post-market study. We look forward to completing these final requirements and working with the FDA towards HDE approval."

The HDE pathway is specifically designed for devices targeting rare diseases or conditions affecting fewer than 8,000 individuals annually in the United States. Under this approval, OncoSil Medical is authorised to commercially market and sell the OncoSil™ device in the US for this indication, subject to oversight conditions standard under the HDE framework. dCCA is associated with particularly poor clinical outcomes, limited treatment options, and an average life expectancy of six months for patients who do not receive treatment for their disease[1].

The Company intends to submit the requested information within the FDA's prescribed timeframe and will continue to keep shareholders informed of any material developments.

Investor webinar

OncoSil Medical will be hosting an investor webinar at 10.30 am AEST today, where the Company's CEO & Managing Director Nigel Lange will discuss the significance of the HDE process and the preliminary results of the TRIPP-FFX trial (separate ASX announcement today). Investors wanting to register to attend this webinar can use the following link:

https://us02web.zoom.us/webinar/register/WN_JHEJ453JQe2g1BENlQ47PA

After registering, you will receive a confirmation email containing information about joining the webinar.

Authorisation & Additional Information

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

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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[2]. 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 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.

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] https://gco.iarc.fr/en