ASX Announcement

1 June 2026

Update on TRIPP-FFX Clinical Trial Results Timing

Sydney, Australia – 1 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), today provides an update on the expected timing for results of the TRIPP-FFX clinical trial.[1]

The Company remains on track to announce the initial results of the trial to the market **prior to the end of the current quarter (4Q FY26)**.

The TRIPP-FFX study is a prospective, non-comparative, randomised multi-centre clinical trial evaluating the safety and efficacy of the OncoSil™ device when used in addition to standard-of-care FOLFIRINOX chemotherapy in patients with unresectable LAPC. The primary endpoints of the trial are Safety and Tolerability in addition to Local Disease Control Rate (LDCR) at 16 weeks. Secondary endpoints include Local Progression-Free Survival (LPFS), Progression-Free Survival (PFS), Overall Survival (OS), and other efficacy measures. Participating centres recruited a total of 88 patients into the trial across 15 sites in Europe and Australia.

As a non-comparative clinical trial, TRIPP-FFX was designed in accordance with the clinical evidence requirements for an existing CE Mark registration under the European Union Medical Device Regulation (EU MDR). Consistent with the regulatory pathway for active implantable medical devices, the study was intentionally designed to evaluate safety and generate supportive evidence of clinical benefit, rather than to conduct a statistically powered superiority trial between treatment arms, as the latter would require a substantially greater number of patients and take significantly longer to complete.

Accordingly, the study was **not** prospectively powered to demonstrate statistically significant differences between study arms on efficacy endpoints and such analyses will not be performed and hence **p-values will not be reported** once the data is available and reported to ASX**.**

This approach is wholly consistent with the EU MDR framework for active implantable medical devices, under which clinical evidence is assessed on the basis of an overall benefit-risk evaluation conducted by an EU Notified Body. The Company believes the TRIPP-FFX study design is appropriate for its intended regulatory objective and consistent with the clinical evidence requirements applicable to active implantable medical devices under EU MDR. Designing the trial in this manner is reflective of the fact that the OncoSil™ device already has received regulatory approval (CE Mark) in Europe (April, 2020).

[1] The trial will continue for long-term overall survival data collection

Subject to the outcome(s) of the trial, the Company expects to file a regulatory submission in late CY2026 that would, if successful, extend the Company's current EU MDR approval for the OncoSil™ device (as a Class III Active Implantable Medical Device) by broadening the chemotherapy regimens within the indications for use to allow FOLFIRINOX as an additional chemotherapy option for patients with unresectable LAPC, in addition to its current approved use with gemcitabine-based chemotherapy

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 (32P) 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[1]. 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/

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

About TRIPP-FFX

TRIPP-FFX (TaRgeted Intratumoural Placement of Phosphorous-32 + FOLFIRINOX) is an open-label, multi-centre, randomised clinical investigation evaluating the safety and efficacy of the OncoSil™ device when used in addition to FOLFIRINOX chemotherapy, versus FOLFIRINOX alone, in patients with unresectable locally advanced pancreatic adenocarcinoma. The study enrolled 88 patients across 15 sites in Europe and Australia on a 1:1 randomisation basis. Primary endpoints are safety and tolerability and Local Disease Control Rate at 16 weeks. Secondary endpoints include overall survival, tumour response rate, surgical resection rate, quality of life, and pain scores. For further details of the trial, please visit: https://clinicaltrials.gov/study/NCT05466799