ASX Announcement

9 June 2026

TRIPP-FFX Clinical Trial Meets Co-Primary Endpoints

Highlights

- **TRIPP-FFX study meets both co-primary endpoints of safety/tolerability and local disease control rate (LDCR) at 16 weeks in patients with unresectable locally advanced pancreatic cancer (LAPC).**
- Investigators concluded that toxicities associated with the addition of OncoSil™ to FOLFIRINOX chemotherapy were limited and manageable.
- Encouraging efficacy outcomes observed, including an **82.2% (95% CI 68-92%) LDCR at 16 weeks** and **18.3 months of median overall survival** in patients treated with OncoSil™ plus FOLFIRINOX.
- The positive TRIPP-FFX results support the rapid progression of the planned Change Notification submission to an EU & UK Notified Body in late 2H CY26 to expand the OncoSil™ label to include use alongside FOLFIRINOX, **a current standard-of-care chemotherapy regimen.**
- Subject to regulatory approval, inclusion of FOLFIRINOX on the OncoSil™ label is **expected to align with current chemotherapy treatment practice, simplify patient referral pathways and support broader commercial adoption.**

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 the TRIPP-FFX clinical study has **met** its co-primary endpoints of safety/tolerability and LDCR at 16 weeks in patients with unresectable LAPC. The study demonstrated encouraging LDCR and survival with limited and manageable toxicities following the addition of OncoSil™ device to standard-of-care FOLFIRINOX chemotherapy. These results confirm the necessary safety and efficacy requirements of adding the OncoSil™ device in addition to FOLFIRINOX, the current standard-of-care chemotherapy regimen for patients with unresectable LAPC.

As a result, the Company will proceed as rapidly as possible to complete the necessary regulatory filing with an EU & UK Notified Body (expected in late 2H CY26) to expand the current CE Mark for the OncoSil™ device to include FOLFIRINOX as an additional chemotherapy option for patients with unresectable LAPC, in addition to its current approved use with gemcitabine-based chemotherapy.

Michele Milella, Professor of Medical Oncology, University of Verona, Italy and Principal Investigator of TRIPP-FFX Study said:

"The TRIPP-FFX study successfully meeting both primary endpoints is an important outcome and represents a significant milestone in the clinical development of the OncoSil™ device for patients with unresectable locally advanced pancreatic cancer. Demonstrating both a favourable safety and tolerability profile together with strong local disease control at 16 weeks provides further validation of this treatment approach.

As TRIPP-FFX was designed as a randomized but non-comparative study, the significance of these findings lies in the successful achievement of the predefined clinical endpoints and the consistency of the overall data, with the control arm serving primarily as a benchmark against historical outcomes rather than for direct statistical comparison. In this context, the results are consistent with previously reported findings from historical datasets, including the PANCO trial and the OSPREY Registry and favourably compare with chemotherapy alone or the combination of chemotherapy and other forms of local treatment commonly used in this difficult-to-treat disease setting.

These findings also reinforce the importance of evaluating the OncoSil™ device in addition to FOLFIRINOX, the standard-of-care chemotherapy regimen used in this setting today. We look forward to conducting deeper analysis of the study data, and I would like to sincerely thank the patients, investigators, participating centres and OncoSil Medical for their commitment and collaboration throughout the trial."

Giuseppe Malleo, Associate Professor of Surgery at the University of Verona, Italy and Principal Investigator of TRIPP-FFX Study said:

"The TRIPP-FFX study marks an important step forward in the treatment of unresectable locally advanced pancreatic cancer, particularly from a multidisciplinary care perspective. The achievement of both primary endpoints supports the continued clinical development of the OncoSil™ device and adds to the growing body of evidence generated through previous studies and real-world experience.

From a surgical standpoint, the study confirms the possibility to downstage selected patients towards surgical resection. Further detailed analysis will help us better understand which patients may benefit the most, and I would like to acknowledge the strong commitment of everyone involved in the study, especially the patients and clinical teams whose contribution made these results possible."

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

"Having met both primary endpoints in the TRIPP-FFX study represents a significant milestone for OncoSil Medical and further strengthens the clinical evidence supporting the use of OncoSil™ in patients with unresectable locally advanced pancreatic cancer. The study demonstrated that OncoSil™ can be successfully integrated with FOLFIRINOX chemotherapy, with a manageable safety profile and encouraging efficacy outcomes, reinforcing its potential to address a significant unmet need in this challenging disease setting. I would like to thank the patients, investigators and clinical teams whose commitment and participation made

this important study possible.

Importantly, subject to regulatory approval, the inclusion of FOLFIRINOX within the OncoSil™ label has the potential to remove a key barrier in the patient treatment pathway. Aligning OncoSil™ with the current standard-of-care chemotherapy regimen would make it easier for medical oncologists to identify and refer appropriate patients for treatment, supporting greater integration of OncoSil™ into routine multidisciplinary care and potentially broadening patient access across key markets.

These results are an important step forward in the development of OncoSil™ and provide a strong foundation for our next phase of growth. Subject to regulatory approval, we believe this could further support physician adoption and strengthen our commercial position across key markets. We look forward to presenting the initial results at a major oncology congress and progressing our planned regulatory submission to expand the OncoSil™ label in Europe to include use alongside FOLFIRINOX."

The TRIPP-FFX is an open-label, multi-centre, randomized, non-comparative study of targeted intratumoural placement of OncoSil™ device in addition to FOLFIRINOX chemotherapy versus FOLFIRINOX chemotherapy alone in patients with unresectable LAPC. In total, 88 patients (median age 64; 53.4% male and 46.6% female) were randomised to FOLFIRINOX (n=43) or FOLFIRINOX + OncoSil™ (n=45) [Intent to Treat (ITT) population]; 42 & 45 received FOLFIRINOX, respectively; 40 received OncoSil™ to target tumour. The preliminary data showed:

Safety

- Grade 3 or greater Treatment-Emergent Adverse Events (TEAEs) were reported in 60.9% of patients in FOLFIRINOX arm and 70.7% of patients in FOLFIRINOX + OncoSil™ arm.
- Investigators concluded that toxicities associated with the addition of OncoSil™ were limited and manageable.
- 40 patients treated with OncoSil™ + FOLFIRINOX are statistically sufficient to establish the combination's safety profile.
- The trial was not powered for statistical comparisons between study arms. Outcomes should be evaluated against historical controls.

Efficacy

- In ITT population, LDCR at 16 weeks was 86.0% (95% Confidence Interval (CI) 67-92%) in FOLFIRINOX arm and 82.2% (95%CI 65-90%) in FOLFIRINOX + OncoSil™ arm.
- The study achieved its primary endpoint, demonstrating a meaningful improvement in LDCR at 16 weeks compared with the historical benchmark of 55%.
- Median overall survival was 15.9 & 18.3 [95% CI 10.2-nc & 12.8-22.2] in FOLFIRINOX and FOLFIRINOX + OncoSil™ arms, respectively.

- In ITT population, best overall response was Partial Response in 41.9% & 57.8%, Stable Disease in 48.8% & 33.3% and Progressive Disease in 9.3% & 8.9% in FOLFIRINOX and FOLFIRINOX + OncoSil™ arms, respectively.
- Median local progression-free survival (mLPFS) was 11.8 & 12.9 [95% CI 7.8-not calculable (nc) & 7.8-nc] months in FOLFIRINOX and FOLFIRINOX + OncoSil™ arms, respectively.
- Median progression-free survival PFS was 9.9 & 12.1 [95% CI 7.5-nc & 7.8-15.2] months in FOLFIRINOX and FOLFIRINOX + OncoSil™ arms, respectively.
- Surgical resection was completed in 14.0% & 11.1% for FOLFIRINOX and FOLFIRINOX + OncoSil™ arms, respectively, with R0 margins in 16.7% & 60% of these resections.
- The study was not designed to compare outcomes between treatment groups; therefore, efficacy results should be interpreted against the historical control rather than between study arms.

The study met the primary endpoints; with the Principal Investigators of the trial concluding there were limited and manageable toxicities and encouraging LDCR and survival endpoints following the addition of OncoSil™ microparticles to FOLFIRINOX chemotherapy. For LDCR, the primary efficacy endpoint, the pre-specified success criterion for the trial required the lower bound of the 95% confidence interval to exceed the 55% threshold and the interval to reach the 75% target. The observed result of a 95% confidence interval of 68% to 92% satisfied both conditions decisively. In other words, the entire range of plausible outcomes sits above 55%, and the interval comfortably spans the 75% benchmark. No direct statistical comparison of the two treatment arms was planned for the trial. As indicated from the ASX announcement dated 1 June 2026, 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.

The Safety Review Committee (SRC) conducted scheduled safety reviews throughout the trial and approved continuation of the study at each assessment. Following review of the safety data, the Principal Investigators concluded that the addition of OncoSil™ to FOLFIRINOX was safe and demonstrated an acceptable tolerability profile. These findings support the conclusion that the study met its safety endpoint.

The TRIPP-FFX results are consistent with the growing body of clinical evidence supporting the use of OncoSil™ in unresectable LAPC. The study met both co-primary endpoints and delivered efficacy outcomes that compare favourably with previously reported OncoSil™ clinical studies and real-world datasets, while also aligning with historical outcomes observed in this disease setting.

The consistency of local disease control, survival outcomes and manageable safety profile across multiple studies reinforces confidence in the reproducibility of the OncoSil™ treatment approach and further strengthens the clinical rationale for expanding its use alongside FOLFIRINOX, the current standard-of-care chemotherapy regimen for LAPC patients.

	PanCO [1]	Meta-Analysis of Phase 2/3 Trials [2]	TRIPP-FFX	
	gemcitabine + nab-paclitaxel or FOLFIRINOX + OncoSil™ (ITT; n=50)	Chemotherapy or Chemo-radiotherapy (n~6,000 across 74 study arms)	FOLFIRINOX (ITT; n=43)	**FOLFIRINOX + OncoSil™ (ITT; n=45)**
LDCR at 16 weeks (95% CI)	82.0% (68.6–91.4%)	not reported	86.0% (72–95%)	**82.2% (68–92%)**
Best Overall Response				
Partial Response	29.8%	19.2%	41.9%	**57.8%**
Stable Disease	66.0%	not reported	48.8%	**33.3%**
Progressive Disease	4.3%	not reported	9.3%	**8.9%**
Disease Control Rate	90.0%	75.6%	90.7%	**91.1%**
Surgical Resection	23.8%	8.0%	14.0%	**11.1%**
R0 margins**	80%	not reported	16.7%	**60%**
Local PFS, median months (95% CI)	9.9 (7.3–12.6)	not reported	11.8 (7.8–nc)	**12.9 (7.8–nc)**
PFS, median months (95% CI)	9.3 (5.7–11.3)	7.8 (7.1–9.1)	9.9 (7.5–nc)	**12.1 (7.8–15.2)**
Overall Survival, median months (95% CI)	15.2 (11.3–18.8)	13.6 (12.7–13.9)	15.9 (10.2–nc)	**18.3 (12.8–22.2)**

* R0 margin: complete microscopic removal of the tumour.

	PanCO [1]	TRIPP-FFX	
	gemcitabine + nab-paclitaxel or FOLFIRINOX + OncoSil™ (PP – Safety Cohort)	FOLFIRINOX (Safety Cohort)	**FOLFIRINOX + OncoSil™ (Safety Cohort)**
Grade ≥3 AEs	81.0%	60.9%	**70.7%**

The positive results from TRIPP-FFX represent a significant milestone in the clinical development program for OncoSil™. The TRIPP-FFX study represents the first prospective randomised evaluation of OncoSil™ in addition to FOLFIRINOX, the current standard-of-care chemotherapy regimen for many patients with unresectable LAPC. FOLFIRINOX is widely regarded as the standard-of-care chemotherapy regimen for fit patients with unresectable LAPC in many major oncology markets.

Having met both co-primary endpoints strengthens the clinical evidence supporting the use of OncoSil™ alongside FOLFIRINOX and provides the basis for a planned Change Notification submission to expand the Company's product label. If approved, inclusion of FOLFIRINOX within the OncoSil™ label would align the device with contemporary treatment practice and has the potential to support broader adoption across key markets.

Next steps

The TRIPP-FFX results establish a clear pathway for further regulatory and commercial development of OncoSil™. The Company intends to:

- Present the initial results at an upcoming major oncology congress (2H CY26)
- Submit a Change Notification to the Company's EU & UK Notified Body in late 2H CY26 to add

FOLFIRINOX to the approved OncoSil™ product label

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 preliminary results of the TRIPP-FFX trial and the updated HDE process with the U.S. FDA (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.

For further information, please contact:

Mr. Nigel Lange CEO & Managing Director E: nigel.lange@oncosil.com T: +49 160 96424981	**Mr. Tim Luscombe & Ms. Nova Taylor** Joint Company Secretaries E: tim.luscombe@bio101.com & nova.taylor@bio101.com T: +61 429 707 079 & +61 414 877 703

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 Phosphorus-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[3]. 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 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. Data presented are preliminary and based on ongoing analyses. Final results may be updated following database lock and completion of all planned statistical analyses. For further details of the trial, please visit: https://clinicaltrials.gov/study/NCT05466799

References:

[1] 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.

[2] OncoSil Medical Ltd. Data on file.

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