ASX Announcement

6 July 2026

TRIPP-FFX Results Presented at ESMO GI 2026 Reinforce Safety and Encouraging Clinical Outcomes

Key Points

- **Updated TRIPP-FFX analysis presented at ESMO GI 2026 demonstrate that the study met both co-primary endpoints of safety/tolerability and local disease control rate (LDCR) at 16 weeks**
- **New, Per Protocol (PP) analysis[1] presented demonstrated a median overall survival of 21.3 months for patients treated with OncoSil™ device plus FOLFIRINOX chemotherapy; median overall survival was 15.6 months in patients treated with FOLFIRINOX chemotherapy alone**
- **PP analysis also demonstrated a 12.5% surgical resection rate, with 60% of resected OncoSil™ device treated patients showing complete surgical removal of their cancer (R0 margin); 7.3% resection rate at 33% RO margin for FOLFIRINOX only group**
- **Safety remained manageable with no new safety signals identified, consistent with the study meeting its co-primary safety endpoint**

Sydney, Australia – 6 July 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 updated results from the TRIPP-FFX clinical study, including a new, Per Protocol (PP) analysis, were presented as a Rapid Oral Presentation at the European Society for Medical Oncology Gastrointestinal Cancers Congress 2026 (ESMO GI 2026), held in Munich, Germany. The presentation was delivered by Michele Milella, Professor of Medical Oncology at the University of Verona, Italy and co-principal investigator of the study.

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

"Presenting the TRIPP-FFX results at ESMO GI 2026 represents an important milestone for OncoSil Medical and provides the opportunity to share our data with one of the world's leading audiences of gastrointestinal oncology specialists. Importantly, the presentation included new, Per Protocol analysis, which demonstrated a median overall survival of 21.3 months together with encouraging efficacy outcomes across multiple clinically meaningful secondary endpoints. This new analysis further strengthens the clinical evidence supporting the use of the OncoSil™ device alongside FOLFIRINOX in patients with unresectable LAPC.

[1] The per protocol analysis includes patients who actually received the OncoSil™ device to target tumour (n=40). Four patients in the OncoSil™ study arm did not receive the OncoSil™ device and one did not receive any OncoSil™ device in the target tumour, but were included in the intent to treat (ITT) analysis as described below and per ASX release dated 9 June 2026.

The continued demonstration of a manageable safety profile with no new safety signals, together with the encouraging efficacy outcomes presented at ESMO GI, further strengthens our confidence as we progress our planned Change Notification submission to expand the OncoSil™ device label to include FOLFIRINOX, subject to regulatory approval."

The presentation included updated analysis of the Phase II TRIPP-FFX study evaluating the addition of the OncoSil™ device to standard-of-care FOLFIRINOX chemotherapy in patients with unresectable locally advanced pancreatic cancer (LAPC). In addition to confirming the previously announced findings that the study met both co-primary endpoints of safety/tolerability and local disease control rate (LDCR) at 16 weeks, the presentation included a new, Per Protocol analysis.

Per Protocol analysis evaluates outcomes in patients who completed treatment according to the study protocol, providing an assessment of treatment efficacy under the intended conditions of use. When considered alongside the primary intention-to-treat analysis, the Per Protocol results offer complementary evidence that can strengthen confidence in the consistency and robustness of the observed treatment effect.

The Per Protocol analysis demonstrated encouraging efficacy outcomes, including median overall survival of 21.3 months (95% Confidence Interval [CI] 13.8–not calculable [nc]) in patients treated with OncoSil™ device plus FOLFIRINOX. The updated analysis continued to demonstrate encouraging efficacy across multiple secondary endpoints while confirming a manageable safety profile with no new safety signals identified.

Safety

The safety profile remained consistent with the previously announced results, with no new safety signals identified.

- The study continued to meet its co-primary safety endpoint, confirming that adverse events following the addition of OncoSil™ device to FOLFIRINOX were limited and manageable.

Efficacy

Previously announced Intent-to-Treat (ITT) results

The updated analysis confirmed the previously reported efficacy outcomes, including:

- Local Disease Control Rate (LDCR) at 16 weeks: 82.2% (95% CI 67.9–92.0) in the OncoSil™ device + FOLFIRINOX arm, exceeding the predefined efficacy threshold
- Median overall survival: 18.2 months (95% CI 13.8–nc)
- Median local progression-free survival: 12.8 months (95% CI 7.8–nc)
- Median progression-free survival: 12.1 months (95% CI 7.8–15.1)
- Median tumour volume reduction: 57.0% in the FOLFIRINOX arm, 72.1% in the OncoSil™ device + FOLFIRINOX arm

New, Per Protocol (PP) analysis

For the first time, the ESMO GI presentation reported PP analysis, demonstrating encouraging outcomes among patients who completed treatment according to protocol.

- Local Disease Control Rate at 16 weeks: 85.4% (95% CI 70.8–94.4) in FOLFIRINOX arm, 85.0% (95% CI 70.2–94.3%) in the OncoSil™ device + FOLFIRINOX arm
- Median overall survival: 15.6 months (95% CI 10.2–21.0) in FOLFIRINOX arm, 21.3 months (95% CI 13.8-nc)
- Median local progression-free survival: 9.9 months (95% CI 7.8–nc) in FOLFIRINOX arm, 12.8 months (95% CI 11.2–nc) in the OncoSil™ device + FOLFIRINOX arm
- Median progression-free survival: 9.9 months (95% CI 7.5–nc) in FOLFIRINOX arm, 12.1 months (95% CI 7.8–15.1) in the OncoSil™ device + FOLFIRINOX arm
- Best overall response was Partial Response in 36.6% & 60.0%, Stable Disease in 53.7% & 30.0% and Progressive Disease in 9.8% & 10.0% in the FOLFIRINOX and FOLFIRINOX + OncoSil™ device arms, respectively
- Median tumour volume reduction: 55.9% in FOLFIRINOX arm, 72.2% in the OncoSil™ device + FOLFIRINOX arm
- Surgical resection rate: 7.3%, with 33% achieving R0 resection in the FOLFIRINOX arm, 12.5%, with 60% of these achieving R0 resection in the OncoSil™ device + FOLFIRINOX arm.

A summary of the ITT and PP analysis is shown below

	FOLFIRINOX		**OncoSil™ device + FOLFIRINOX**	
	ITT (n=43)	PP (n=41)	ITT (n=45)	PP (n=40)
LDCR at 16 weeks * (95% CI)	86.0% (72.1–94.7)	85.4% (70.8–94.4)	82.2% (67.9–92.0)	85.0% (70.2–94.3)
Best Overall Response *				
Partial Response	37.2%	36.6%	55.6%	60.0%
Stable Disease	51.2%	53.7%	31.1%	30.0%
Progressive Disease	9.3%	9.8%	8.9%	10.0%
Missing	2.3%	0	4.4%	0
Surgical Resection R0 margins	11.6% 16.7%	7.3% 33%	11.1% 60%	12.5% 60%
Tumour Volume, median maximal change	–57.0%	–55.9%	–72.1%	–72.2%
Local PFS,* median months (95% CI)	11.8 (7.8–nc)	9.9 (7.8–nc)	12.8 (7.8–nc)	12.8 (11.2–nc)

PFS,* median months (95% CI)	9.9 (7.8–nc)	9.9 (7.5–nc)	12.1 (7.8–15.1)	12.1 (7.8–15.1)
Overall Survival, median months (95% CI)	15.8 (10.2–nc)	15.6 (10.2–21.0)	18.2 (13.8–nc)	21.3 (13.8–nc)
Follow-Up, median months (95% CI)	12.2 (9.9–17.0)	Not reached	12.4 (11.0–17.0)	Not reached

Initial results. * By blinded independent central review (RECIST 1.1); CI, confidence intervals; nc, non-calculable.

The investigators concluded that TRIPP-FFX successfully met its co-primary endpoints, demonstrating manageable toxicities and local disease control exceeding 80% at 16 weeks following the addition of OncoSil™ device to FOLFIRINOX chemotherapy. The updated analysis presented at ESMO GI, including previously unreported Per Protocol results, demonstrated encouraging efficacy outcomes, with median overall survival of 21.3 months in the OncoSil™ device plus FOLFIRINOX arm. Secondary efficacy endpoints were generally in line with the best outcomes reported in recent studies of locally advanced pancreatic cancer and numerically favoured the OncoSil™ device plus FOLFIRINOX arm across objective response rate, local progression-free survival, progression-free survival, overall survival and R0 resection rates. The safety profile remained manageable, with no new safety signals identified, further supporting the growing body of clinical evidence for the use of OncoSil™ device in combination with standard-of-care FOLFIRINOX chemotherapy in patients with unresectable locally advanced pancreatic cancer.

Following presentation of the TRIPP-FFX initial results at ESMO GI, the Company remains on track to submit a Change Notification to its EU & UK Notified Body in late 2H CY26 to expand the OncoSil™ device label to include use alongside FOLFIRINOX, subject to regulatory approval.

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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 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[Error! Bookmark not defined.]. 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