ASX Announcement

3 December 2025

OSPREY Registry Demonstrates Encouraging Survival for OncoSil™ Plus Chemotherapy in Unresectable Locally Advanced Pancreatic Cancer Patients

Key Highlights:

- First interim analysis of the OSPREY registry of 64 unresectable LAPC patients treated with the OncoSil™ device and gemcitabine-based chemotherapy in routine clinical practice across 19 centres in Europe
- In first-line patients (75% of all patients), median Overall Survival was 20.6 months from diagnosis for those implanted with OncoSil™ at ≤4 months from starting chemotherapy, and 22.0 months from diagnosis for those implanted with OncoSil™ at 4–12 months from starting chemotherapy
- In total, 15.6% of patients reported Adverse Device Events (ADEs), with all ADEs considered mild with no serious ADEs, no acute complications, no pancreatitis and no patient required hospital admission
- Data submitted for potential acceptance at the European Society of Gastrointestinal Endoscopy (ESGE) Days congress which will be held 14–16 May 2026 in Milan, Italy

Sydney, Australia – 3 December 2025: 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 announces the submission of the first interim clinical data from the real-world OncoSil™ Pancreatic Cancer Post-Marketing Clinical Registry (OSPREY), sponsored by the Company.

The interim findings from the OSPREY registry demonstrate a highly encouraging overall survival profile for patients with unresectable LAPC treated with the OncoSil™ device in routine clinical practice. Historically, overall survival for patients receiving **gemcitabine + nab-paclitaxel as first-line therapy alone** have reported medians in the range of **12.7 to 18.8 months** in prospective clinical trials in unreseactable LAPC patients[1, 2, 3] and OncoSil Medical's propensity score analysis, which showed significant survival advantage compared to patients receiving chemotherapy alone[4].

Against this backdrop, the **20.6 and 22.0 month median overall survival observed in first-line patients** within the OSPREY registry represents a marked improvement. Local Disease Control Rate at 12 weeks post-implant was 91.7% for first-line patients and 77.8% at second-line with 7 patients having their tumours surgically resected with curative intent.

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

"We welcome the preparation of this initial interim data by the OSPREY clinical investigators, and we very much look forward to presenting these encouraging data to a significant number of endoscopists attending the 2026 ESGE Days meeting, particularly given the lack of safe and effective interventions in unresectable LAPC where survival rates are poor and effective therapies desperately needed."

Importantly, these outcomes align closely with the totality of evidence generated across the Company's clinical development program, including the PanCO trial, which have demonstrated extended survival and a favourable safety profile when OncoSil™ is used in addition to standard chemotherapy and Real-World Evidence, such as the propensity score weighted landmark analysis, which reported a significant survival advantage for patients receiving OncoSil™ plus chemotherapy compared to chemotherapy alone (median overall survival: 19.7 *vs*. 12.0 months; p=0.002)[4].

The OSPREY data is also consistent with the recent findings of the PANCOSIL Phase 1-2 study, a first in the world study administering OncoSil™ via direct injection through the skin (percutaneous) under CT-imaging guidance for LAPC, which showed median overall survival of 20.6 months.[5]

The safety findings in OSPREY—characterised by a low incidence of device-related events, all of which were mild, transient and resolved without clinical sequelae, with no serious device-related complications reported—reinforce the predictable and manageable clinical profile of the therapy.

An abstract summarising key findings titled:

"OSPREY Registry: First Interim Analysis of Patients with Unresectable Locally Advanced Pancreatic Cancer Treated with EUS-Guided Phosphorus-32 Microparticles plus Gemcitabine-Based Chemotherapy in Routine Clinical Practice"

Has just been submitted for acceptance at the ESGE Days congress to be held in Milan, Italy from 14-16 May 2026. OncoSil Medical intends to make a further ASX announcement if the submission is successful and the data will be formally presented at the meeting by OSPREY investigators, which is anticipated in February 2026.

OSPREY is a post-market, multi-centre, observational, prospective registry in which data is recorded from patients with unresectable LAPC receiving gemcitabine-based chemotherapy who had Endoscopic Ultrasound (EUS)-guided implantation of the OncoSil device as part of their routine clinical care. Enrolment commenced April 2022 and is ongoing. Registry objectives include safety/tolerability (Adverse Device Effects [ADEs] possibly or probably related to 32P device and/or implantation) and efficacy outcomes.

Ends.

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, Turkey and Israel, with commercial treatments using the device already undertaken in Germany, Spain, Portugal, Italy, Austria, Greece, Turkey, and Israel.

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

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

About ESGE Days

ESGE Days is a multi-day event providing an inspiring environment for the whole endoscopy community to interact, discuss, debate and learn about the latest advances in endoscopy. It has a cutting-edge scientific programme that brings together live demonstrations, a wide variety of session types, specialized symposia and hands-on training.

References

1. Cascinu S, Berardi R, Bianco R et al. Nab-paclitaxel/gemcitabine combination is more effective than gemcitabine alone in locally advanced, unresectable pancreatic cancer - A GISCAD phase II randomized trial. Eur J Cancer. 2021 May;148:422-429. doi: 10.1016/j.ejca.2021.02.023.
2. Babiker HM, Picozzi V, Chandana SR et al. Tumor treating fields with gemcitabine and nab-paclitaxel for locally advanced pancreatic adenocarcinoma: randomized, open-label, pivotal phase III PANOVA-3 study. J Clin Oncol 2025. doi:10.1200/JCO-25-00746
3. Philip P, Lacy J, Portales F et al. Nab-paclitaxel plus gemcitabine in patients with locally advanced pancreatic cancer (LAPACT): a multicentre, open-label phase 2 study. Lancet Gastroenterol Hepatol 2020; 5: 285–94, doi: 10.1016/S2468-1253(19)30327-9
4. Lim A, Nitchingham D, Bednarz J et al. Combined phosphorus-32 implantation and chemotherapy alone for locally advanced pancreatic cancer: a propensity-score weighted landmark analysis. Gastrointestinal Endoscopy 2025 May 8. doi: 10.1016/j.gie.2025.04.054
5. See ASX announcement dated 21 September 2025