ASX Announcement

28 May 2026

OncoSil Medical Secures Key Ethics Approval for Italian Patient Registry

Establishing procurement framework in Italy

Key Highlights:

- **Central Italian ethics committee approval received for OncoSil Medical's OSPRItaly registry to be classified as an observational clinical registry from an interventional registry.**
- **Updated ethics approval enables participating hospitals to purchase the OncoSil™ device directly through a negotiated procedure tendered process.**
- **Streamlines onboarding and procurement pathways and is expected to support broader commercial rollout (100% increase in authorised hospitals in 1H FY27) and increased adoption across Italy.**
- **Reimbursement for the OncoSil™ device implantation procedure now recognised within Italy's legal and regulatory framework.**
- **Italy represents a significant European market opportunity, with more than 16,000 new pancreatic cancer cases diagnosed annually.[1]**

Sydney, Australia – 28 May 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 Comitato Etico Territoriale (CET) Lazio Area 4 (Lazio Area 4 Territorial Ethics Committee) approval has been received in Italy for OSPRItaly post-market clinical registry. This classification is significant as it enables participating hospitals and treatment centres to access OncoSil™ device directly through a simplified and expedited process. This will reduce administrative complexity associated with site participation and support a more effective purchasing pathway.

The approval removes the requirement for separate ethics approvals at individual hospitals, significantly simplifying onboarding and enabling faster and broader access to commercial treatment centres throughout Italy. This approval is expected to support broader commercial rollout and increased adoption of the OncoSil™ device across Italy. The reimbursement of the OncoSil™ device standardised implantation procedure across the Italian market is now accepted within the legal framework. Additionally, hospitals are now free to purchase the OncoSil™ device via a non-competitive negotiated procedure (single product).

With the acknowledgement of the OSPRItaly registry, CET Lazio Area 4 has recognised the OncoSil™ device for standard clinical practice in Italy. CET Lazio Area 4 will act as the coordinating Ethics Committee (EC), enabling additional clinical sites to be added through an expedited amendment process, specifically referencing the CET Lazio Area 4 central approval.

OncoSil Medical currently has four authorised treatment centres in Italy. The streamlined approval framework is expected to facilitate the onboarding of an additional four hospitals over the next two quarters, materially expanding the Company's potential treatment network within the Italian market. The company expects to add further hospitals in Q1 CY27.

The approval is particularly significant given Italy is one of the larger pancreatic cancer treatment markets in Europe, with more than 16,000 new pancreatic cancer cases diagnosed annually.

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

"This approval represents an important commercial milestone for OncoSil Medical in Italy. By enabling treatment centres to participate through a simplified and expedited process, we believe this will facilitate broader adoption of the OncoSil™ device across the market and improve patient access to treatment.

Importantly, the non-interventional classification of the registry supports a simpler and more efficient purchasing pathway for participating hospitals, which we believe will strengthen adoption and enhance the commercial opportunity for the OncoSil™ device in Italy.

Italy is an important strategic market for the Company in Europe, and the potential for this approval to drive broader commercial rollout across one of Western Europe's largest healthcare markets is an exciting development."

OncoSil Medical continues to work closely with clinicians and healthcare institutions across Europe to expand patient access to the OncoSil™ device and generate further post-market clinical evidence supporting its use in pancreatic cancer treatment. This approval confirms that OncoSil™ is being independently selected by clinicians as part of routine care, a meaningful indicator of real-world clinical acceptance.

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 (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/

About the OSPRItaly Patient Registry

The OSPRItaly Patient Registry is a multi-centre clinical registry designed to collect real-world safety and performance data on the OncoSil™ device when used within the regulatory approved indication of unresectable LAPC, in combination with gemcitabine-based chemotherapy. The OSPRItaly registry was initiated in May 2024 and is being conducted at select sites across Italy, with approximately 50 patients targeted for enrolment.

References

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