ASX Announcement

20 May 2026

OncoSil Medical Receives TGA Approval for OncoSil™ Device in Australia

Key Highlights:

- **TGA approval received for the OncoSil™ device for the treatment of pancreatic cancer in Australia**
- **First and only TGA approved Class III medical device targeting tumours directly within the pancreas**
- **Large and growing market with 4,353 new pancreatic cancer cases each year, representing the 8th most common cancer in Australia**

Sydney, Australia – 20 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 that it has received approval from the Australian Therapeutic Goods Administration (TGA) for the OncoSil™ device for the treatment of LAPC in addition to gemcitabine-based chemotherapy. The OncoSil™ device has been included on to the Australian Register of Therapeutic Goods (ARTG).

The TGA approval represents a major milestone for the Company and opens the way for commercialisation of the OncoSil™ device in Australia. Importantly, this achievement marks the approval of an innovative Australian-developed medical technology in its home market and reinforces Australia's position as a global leader in advanced oncology innovation.

Pancreatic cancer remains one of the deadliest forms of cancer globally, with limited treatment options and poor survival outcomes. In Australia alone, there are approximately 4,353 new pancreatic cancer patients diagnosed each year[1]. The approval provides Australian clinicians and patients with access to a novel treatment option for this highly challenging disease.

The approval is expected to support broader market adoption, strengthen clinician engagement, further validate the growing body of clinical evidence supporting the OncoSil™ device, and will also support future regulatory approvals in additional international markets.

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

"Receiving TGA approval is a defining moment for OncoSil Medical and an especially proud achievement as an Australian medical technology company. Having developed this innovative treatment platform in Australia, it is incredibly significant to now secure approval in our home market. This milestone not only validates the strength of our clinical and regulatory work but also enables Australian patients suffering from one of the most difficult-to-treat cancers to gain access to a new therapeutic option. We believe this approval will further accelerate clinical adoption and strengthen our global commercialisation strategy.

"Securing TGA approval is a defining milestone for OncoSil Medical and a strong validation of the Company's clinical and regulatory strategy, as a class III device like ours is subject to the most stringent regulatory review process for medical devices. As an Australian-developed medical technology, achieving approval in our home market is particularly significant and reflects the dedication of our team, investigators and clinical partners over many years. Importantly, this approval provides Australian clinicians and patients with access to a new treatment option for pancreatic cancer and further strengthens the Company's global commercialisation strategy.

"This milestone is further supported by the near completion of our new manufacturing facility in Macquarie Park, Sydney, in partnership with Cyclotek, which is expected to strengthen OncoSil Medical's domestic and global supply chain capabilities as the Company scales commercial operations."

Professor Nam Nguyen, Head of Endoscopy at the Royal Adelaide Hospital and Clinical Professor at Adelaide University, said:

"Pancreatic cancer remains one of the greatest unmet needs in oncology, and the availability of the OncoSil™ device in Australia is an important advancement for clinicians and patients. For Australian patients suffering from locally advanced pancreatic cancer (LAPC), where treatment options are often limited, access to new technologies such as OncoSil™ is particularly important.

"Based on our extensive experience with the OncoSil™ device, it has demonstrated significant potential value in helping drive patients towards surgical eligibility, which remains one of the most important determinants of long-term outcomes in pancreatic cancer. In addition, the targeted nature of the treatment may provide an important additional survival benefit when integrated into multidisciplinary treatment pathways. TGA approval is a significant milestone that recognises both the innovation and potential clinical value of this therapy."

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** **Company Secretary** **E: tim.luscombe@bio101.com** **T: +61 429 707 079**

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, 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