

ASX Announcement

20 July 2026

OncoSil Medical Receives Saudi FDA Approval

Key highlights

- The OncoSil™ device has received approval from the Saudi Food and Drug Authority (Saudi FDA) after successfully completing the regulatory process, enabling OncoSil Medical commercial access to the largest healthcare market in the Middle East.
- Saudi nationals can now access the OncoSil™ device treatment with full reimbursement.
- Saudi Arabia traditionally serves as a regional referral hub for patients from across the GCC (Gulf Cooperation Council) and the wider Middle East.

Sydney, Australia – 20 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 it has successfully completed the regulatory approval process in the Kingdom of Saudi Arabia, with the OncoSil™ device receiving approval from the Saudi Food and Drug Authority (Saudi FDA).

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

“Receiving Saudi FDA approval is an important step in our commercial expansion across the Middle East. Saudi Arabia represents the largest healthcare market in the region, and this approval enables eligible patients to access our technology through the national reimbursement system without personal financial burden.

We also see significant potential for Saudi Arabia to serve as a regional referral hub, with patients from across the Gulf and the broader Middle East travelling to leading Saudi hospitals for advanced cancer treatment.”

This milestone represents a significant commercial achievement for OncoSil Medical and opens access to one of the most important healthcare markets in the Middle East. Saudi Arabia is the region's largest healthcare market, supported by substantial government investment in advanced medical technologies and cancer care.

Importantly, with Saudi FDA approval now in place, eligible Saudi nationals will have access to OncoSil™ device treatment through the Kingdom's reimbursement system, enabling patients to receive treatment without out-of-pocket cost. This removes a significant barrier to access and supports broader adoption of the therapy across the country.

Enabling reimbursed patient access to the Middle East's largest healthcare market

Saudi Arabia has been recognised as a leader in innovative medical care throughout the region. Patients from neighbouring GCC countries and the wider Middle East frequently seek specialist medical care in Saudi Arabia, creating an opportunity to expand patient access to the OncoSil™ device beyond the domestic market.

OncoSil Medical acknowledges the outstanding support and commitment of its exclusive distribution partner, Abdulla Fouad Group, whose dedication and expertise were instrumental in successfully navigating the regulatory approval process in bringing the OncoSil™ device to the Saudi market.

The Company looks forward to working closely with Abdulla Fouad Group, healthcare providers and key opinion leaders throughout Saudi Arabia to commence commercial rollout and provide patients with access to OncoSil Medical's innovative treatment.

Click [here](#) to view this announcement on Investor Hub

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 year¹. 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>