

ASX Announcement

30 April 2025

Tender Process for CRO to Undertake G-BA Study Commences

Sydney, Australia – 30 April 2025: Pancreatic cancer treatment device company **OncoSil Medical Limited** (ASX:OSL) (“OncoSil” or “the Company”) is pleased to announce that the Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) in Germany has officially initiated a European-wide tender process to identify and appoint a Contract Research Organisation (CRO). The selected CRO will be responsible for the design and conduct of the study on behalf of G-BA.

The study will assess the implantation of the OncoSil™ device via endoscopic ultrasound guidance in addition to standard of care chemotherapy versus standard of care chemotherapy alone for the treatment of unresectable, locally advanced pancreatic cancer (LAPC) in a randomised design.

This significant milestone reflects the continued engagement of the G-BA with OncoSil’s innovative technology and marks a critical step forward in the process towards potential inclusion in the German treatment guidelines and statutory health insurance system.

The tender details are publicly available through the G-BA's official channels (<https://ted.europa.eu/en/notice/-/detail/260203-2025>), which outlines the scope of work and expected timelines for the clinical evaluation. The tender is open for submissions until 11 June 2025.

The outcome of this study will form a key component of the evidence required by G-BA to consider a positive reimbursement decision for the OncoSil™ device in Germany.

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

"We are pleased to see the G-BA progressing with the announcement of this tender. It represents a crucial step towards the generation of clinical evidence under the Testing Directive. We look forward to the next steps in this pathway and, ultimately, the commencement of the study."

Authorisation & Additional Information

This announcement was authorised by the CEO & Managing Director of OncoSil Medical Limited.

For further information, please contact:

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About OncoSil Medical

OncoSil Medical Limited (ASX:OSL) has developed a cancer treatment device, the OncoSil™ brachytherapy device, which is a critical component of a revolutionary brachytherapy treatment for locally advanced unresectable pancreatic cancer. This type of cancer is the 12th most common cancer in men and the 11th most common cancer in women across the globe, with some 500,000 new cases of pancreatic cancer detected every year. With pancreatic cancer typically diagnosed at a later stage, it has a poor prognosis for long-term survival¹.

The OncoSil™ device delivers a targeted intratumoural placement of Phosphorous-32 (³²P) in the treatment of locally advanced unresectable pancreatic cancer. This occurs via injection directly into a patient's pancreatic tumours under endoscopic ultrasound guidance and takes place in combination with gemcitabine-based chemotherapy.

The OncoSil™ device that has already received breakthrough device designation in the European Union, United Kingdom and United States for the treatment of locally advanced unresectable pancreatic cancer in combination with chemotherapy. CE Marking has additionally been granted for the OncoSil™ device, which can be marketed in the European Union, United Kingdom.

While clinical trials involving the OncoSil™ device continue to occur, the Company is simultaneously moving to commercialise this unique medical technology. It is currently approved for sale in 30+ countries including European Union, United Kingdom, Türkiye and Israel, with initial commercial pancreatic cancer treatments using the device already undertaken in Spain, Italy and Israel.

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

References: 1. <https://www.wcrf.org/cancer-trends/pancreatic-cancer-statistics/>

About the Federal Joint Committee (G-BA)

The Federal Joint Committee (G-BA) is the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany. It issues directives for the benefit catalogue of the statutory health insurance funds (GKV) for more than 74 million insured persons and thus specifies which services in medical care are reimbursed by the GKV.

To learn more, please visit: <https://www.g-ba.de/>