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**ASX Announcement**

**28 January 2025**

# OncoSil Medical Receives MDR Approval

**Sydney, Australia – 28 January 2025:** Pancreatic cancer treatment device company **OncoSil Medical Limited (ASX:OSL)** ("**OncoSil**" or "**the Company**") is pleased to announce that it has received Medical Device Regulation (MDR) certification from BSI, the EU Notified Body. The certification includes the lifting of existing post-market restrictions. This milestone highlights the growing robust clinical evidence supporting the safety of the OncoSil™ device and marks a significant step forward for the company.

The removal of these post-market restrictions will have a transformative impact on OncoSil's operations. By eliminating local ethics and hospital governance approvals, OncoSil simplifies the initiation of commercial treatments, enabling smoother operations and allowing teams to focus on advancing commercial activities. The removal of operational constraints is projected to yield significant cost savings over the next three years, which will be reinvested in growth initiatives and strategic advancements of the OncoSil™ device. Simplified approval pathways further accelerate market access, shortening sales cycles and expanding the reach of the OncoSil™ device across the EU and UK, enhancing patient access and driving commercial success.

MDR certification also provides a critical opportunity to re-submit our application to the Therapeutic Goods Administration (TGA) for approval in the Australian market, aligning with our commitment to improving global patient outcomes.

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

*"Receiving MDR approval is a pivotal achievement for OncoSil Medical. It underscores the strength of our clinical evidence and the safety profile of the OncoSil™ device. With the lifting of post-market restrictions, we are now in a stronger position to streamline operations, focus on commercial growth, and accelerate market access across key European markets. Importantly, this milestone allows us to revisit opportunities in the Australian market, reinforcing our mission to bring life-changing treatments to more patients worldwide."*

**Authorisation & Additional Information**

This announcement was authorised by the Chairman of OncoSil Medical Limited.

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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 survival[1].

The OncoSil™ device delivers a targeted intratumoural placement of Phosphorous-32 ($^{32}P$) 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/