ASX Announcement

24 October 2024

G-BA Approval received for OncoSil™ Device

Sydney, Australia – 24 October 2024: Pancreatic cancer treatment device company **OncoSil Medical Limited (ASX:OSL)** ("**OncoSil**" or "**the Company**") is pleased to announce a significant milestone.

Next step for fully reimbursed clinical trial approved by German Federal Joint Committee (G-BA)

OncoSil is pleased to announce that it has been informed that the German Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) approved the Directive for testing the new treatment method: "Endoscopic injection-implantation of 32P-labeled microparticles in unresectable, locally advanced pancreatic tumors." This decision establishes the legal foundation for a randomized controlled trial conducted under the framework of a Coverage with Evidence Development (CED) program, which allows for the treatment to be conditionally reimbursed while additional evidence is gathered to support its effectiveness. The trial is designed to demonstrate the patient-relevant benefits of this method compared to standard first-line chemotherapy.

This development marks a key step in advancing OncoSil's innovative approach, which will significantly impact the treatment landscape for pancreatic cancer patients.

In addition, Oncosil provides the following updates on MDR and FDA.

Update on MDR Draft Approval for OncoSil™ Device

OncoSil advises that it has received draft notification of Medical Device Regulation (MDR) approval for the OncoSil™ device. This approval will also include the lifting of existing post-market restrictions (OSPREY registry), a significant milestone that underscores the robust clinical evidence supporting the safety of the OncoSil™ device.

The removal of these restrictions will relieve the company of a considerable administrative burden by eliminating the need for ongoing registry compliance and reporting requirements for new sites and patients, previously imposed under the post-market restrictions. This will remove the need for local ethics and hospital governance approvals prior to starting commercial treatments, as well as post-treatment data collection and monitoring processes. This will permit our teams to focus more effectively on commercial business activities.

Additionally, the removal of restrictions will result in significant cost savings over the next three years by reducing the operational expenses associated with maintaining compliance. These savings will free up financial resources that can be reallocated to support growth initiatives and strategic investments.

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Moreover, this approval will significantly shorten the sales cycle by simplifying the approval pathway, allowing for faster market access. It also enables us to streamline operations and concentrate efforts on expanding market reach and patient access in the EU and UK, further driving the commercial success of the OncoSil™ device.

MDR approval will also provide us with the opportunity to re-submit our application to TGA for approval in the Australian market.

Update on Ongoing FDA Discussions

OncoSil Medical is currently in communication with the US Food and Drug Administration (FDA) regarding its Humanitarian Device Exemption (HDE) Application for the use of OncoSil™ in the treatment of unresectable distal cholangiocarcinoma (dCCA). The Company has provided substantial data to FDA in support of the HDE application. The Agency has requested additional information to support the HDE.

OncoSil Medical is responding at the earliest opportunity to FDA's request and will continue to work with the Agency to expedite approval of the HDE. We are confident that this ongoing engagement will bring us closer to achieving U.S. market approval for the treatment of dCCA, a critical step forward in bringing this innovative therapy to patients in the U.S.

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

"I am very pleased that the G-BA fulfilled its mandate, setting the course for improved care in Germany for patients with pancreatic cancer. The framework for the trial, legally binding after publication the Federal Law Gazette, represents a critical milestone in proving the benefits of OncoSil™ at the highest level of evidence.

Similarly, the MDR approval, alongside the lifting of post-market restrictions, will mark a pivotal moment for OncoSil Medical. It will not only validate the safety and efficacy of our OncoSil™ device but also delivers operational effectiveness by reducing administrative requirements and lowering costs for the company. We are also encouraged by the progress with the FDA and remain confident that continued productive discussions will lead to approval in the U.S., enabling us to provide this much-needed treatment to a broader patient population."

Authorisation & Additional Information

This announcement was authorised by the Chairman 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 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/

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