

ASX Announcement

24 April 2023

Further commercial milestones achieved in Spain

Key Highlights

- ✓ The first patient commercially treated with the OncoSil™ device at the Las Palmas hospital in the Canary Islands, Spain has undergone successful surgical resection of their primary tumour;
- ✓ The Ministry of Health has approved a tender for Las Palmas hospital with a value of €220k (A\$361k);
- ✓ OncoSil expands the number of hospitals treating patients with the OncoSil™ device, with the sixth hospital site, Vall d'Hebron hospital now active in patient treatments; and
- ✓ The Company continues to work with a number of other institutions in Spain to enable increased patient access to treatments with the OncoSil™ device.

Sydney, Australia – 24 April 2023: The Board of OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), a medical device company focused on localised treatments for patients with locally advanced pancreatic cancer (LAPC), is pleased to announce further commercial progress being made in Spain.

The first patient who was commercially treated with the OncoSil™ device at Las Palmas hospital in the Canary Islands, Spain in October 2022 has undergone a successful resection of their primary LAPC tumour this week. Patients who undergo successful resections of their primary tumour show dramatically improved outcomes.

The Ministry of Health has also approved a tender at the Las Palmas hospital in the Canary Islands with a tender valued at €220K (A\$361k). This tender includes a set number of patient doses to be delivered by the hospital which will be subject to renewal once utilised, with standard termination clauses applying.

OncoSil has also expanded the number of sites treating patients with the OncoSil™ device, with the sixth hospital site, Vall d'Hebron treating their first patient.

The sales team in Spain continues to work with other leading hospitals to increase the number of sites who are able to commence patient treatments with the OncoSil™ device for those diagnosed with LAPC.

OncoSil's CEO and Managing Director, Mr Nigel Lange said:

"We are pleased that further patients have undergone resection of their tumours after receiving the OncoSil™ device for the treatment of (LAPC). In the PanCO trial, 23.8% of patients who were treated with the OncoSil™ device were successfully resected and we are encouraged to see this trend continue. I am also pleased with the addition of the sixth hospital in Spain, Vall d'Hebron for the treatment of patients

with LAPC. We continue to work with additional institutions in Spain and throughout Europe to accelerate the use of the OncoSil device for patients suffering from LAPC.”

-ENDS-

Authorisation & Additional Information

This announcement was authorised by the Board of Directors of OncoSil Medical Limited.

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About OncoSil

OncoSil Medical is a medical device company seeking to advance radiation for cancer patients. OncoSil Medical’s lead product, OncoSil™ is a targeted radioactive isotope (Phosphorus-32), implanted directly into a patient’s pancreatic tumours via an endoscopic ultrasound.

Treatment with the OncoSil™ is intended to deliver more concentrated and localised beta radiation compared to external beam radiation. OncoSil Medical has conducted six clinical studies with positive results on tolerability, safety and efficacy. CE Marking has been granted for the OncoSil™ device which can be marketed in the European Union and the United Kingdom. The OncoSil™ device has also been classified a Breakthrough Device in the European Union and the United Kingdom.

An Investigational Device Exemption (IDE) has been granted by the United States Food and Drug Administration (FDA) to conduct a clinical study of the OncoSil™ device aimed at supporting a PMA approval.

In December 2018, the FDA granted Humanitarian Use Designation (HUD) for the OncoSil™ device for the treatment of unresectable bile duct cancer. In March 2020, the FDA granted Breakthrough Device Designation for the OncoSil™ for unresectable pancreatic cancer in conjunction with systemic chemotherapy.

Pancreatic cancer is typically diagnosed at a later stage, when there is a poor prognosis for long-term survival. The World Cancer Research Fund estimated that in 2012, 338,000 people globally were diagnosed with pancreatic cancer. The prognosis for patients diagnosed with pancreatic cancer, regardless of stage, is generally poor; the relative five-year survival rate for all stages combined is approximately 5%. The estimated world-wide market opportunity for OncoSil™ in pancreatic cancer exceeds \$3b.

Forward Looking Statements

This document contains certain forward-looking statements, relating to OncoSil’s business, which can be identified by the use of forward-looking terminology such as “promising”, “plans”, “anticipated”, “will”, “project”, “believe”, “forecast”, “expected”, “estimated”, “targeting”, “aiming”, “set to”, “potential”, “seeking to”, “goal”, “could provide”, “intends”, “is being developed”, “could be”, “on track”, or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA and other authorities’ requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales. In particular, management’s expectations regarding the approval and commercialisation of the product candidates could be affected by, among other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.



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