

ASX Announcement

1 May 2023

First anniversary of the OSPREY post-marketing registry

Key Highlights

- ✓ First year anniversary of the OSPREY patient registry;
- ✓ Local Disease Control Rates $\geq 90\%$ at 12 weeks post-implantation;
- ✓ 30% of patients downstaged to surgery to date;
- ✓ No adverse events reported attributable to the OncoSil™ device; and
- ✓ 90% of these patients treated with the OncoSil™ device still alive at their most recent follow-up.

Sydney, Australia – 1 May 2023: The Board of OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), a medical device company focused on treatments for patients with locally advanced pancreatic cancer (LAPC), is pleased to announce the findings of an analysis of the data contained in the OSPREY patient registry at the first-year anniversary since the first commercial patient data was entered into the registry.

The OSPREY patient registry has been developed to collect and assess the performance and safety data related to the use of the OncoSil™ device when used within the approved indication of unresectable, locally advanced pancreatic cancer, in combination with gemcitabine-based chemotherapy, within a real-world observational registry.

The findings of the analysis of the data in the OSPREY patient registry include the following:

- Local Disease Control Rate is $\geq 90\%$ at 12 weeks post-implantation of the OncoSil™ device;
- 30% of patients were downstaged to surgery to date, although this data remains immature as follow-up assessments of patients after implantation remains ongoing;
- 12 patients have been recruited into the registry during the first year since commercial treatments commenced in the European Union; Of these, 10 patients have at least 12 weeks follow-up post-implantation, with 90% of these patients alive at their most recent follow-up; *and*
- To date, no adverse events reported are attributable to the OncoSil™ device in the patients who have undergone treatment.

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

"Given the poor prognosis of pancreatic cancer patients at diagnosis, I am very pleased with the 90% survival of these patients following treatment with the OncoSil device in the commercial setting in the European Union. I look forward to further growth in the number of patients entered into the OSPREY registry to further confirm the benefits for patients who suffer from this insidious disease."

-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. OncoSil Medical is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.