

ASX Announcement

3 February 2022

OncoSil approved for Innovation Funding (NUB) and Central Ethics for all hospitals in Germany

Key Highlights

- ✓ **The Institute for the Hospital Remuneration System (InEK) has granted the OncoSil device with a “Positive Status 1” classification;**
- ✓ **25 leading university hospital sites in Germany submitted requests for innovation funding (NUB) for the OncoSil device;**
- ✓ **Hospitals which submitted NUB applications can now individually negotiate with Statutory Health Insurance providers (“Sickness Funds”) for reimbursement of the OncoSil™ device for patient treatments; and further**
- ✓ **The University of Cologne Hospital ethics committee has approved the OSPREY Registry, acting as central ethics approval for all hospital sites within Germany.**

Sydney, Australia – 3 February 2022: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**) is pleased to announce that the German institute for the Hospital Remuneration System (InEK) granted the OncoSil™ device with a “Positive Status 1” classification under the innovation funding (NUB) program.

The NUB funding mechanism provides hospitals with additional funding to adopt a method or procedure that uses a new device that is not covered through existing federal hospital funding processes in Germany.

To secure NUB funding, a formal procedure is required whereby each hospital or hospital network is required to apply individually to The Institute for the Hospital Remuneration System (InEK). The InEK approves NUB funding based on a new device’s demonstrated added clinical benefit compared with established procedures and devices and the number of patients being treated with the device. In late 2021, 25 leading university hospital sites in Germany applied to the InEK for inclusion of the OncoSil™ device in the NUB program.

Now that the InEK has approved the OncoSil™ device with a Positive Status 1 NUB classification, the number of devices to be reimbursed, and the reimbursed price and inclusions will be negotiated between each individual hospital and the Statutory Health Insurance (SHI) providers (“sickness funds”). This negotiation process will occur in the near future following the Positive Status 1 classification of the OncoSil™ device.

Furthermore, OncoSil is pleased to announce that the University of Cologne Hospital has approved the OSPREY Registry, acting as the central ethics approvals authority for German hospitals. This process allows for the other 24 hospital sites who have submitted NUB applications to complete their internal ethics processes for the OSPREY registry in an expedited manner.

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

"Receiving a Positive Status 1 classification from the InEK is an important step forward for OncoSil in Germany. The team has been working closely with the leading hospital sites in submitting these applications to the InEK and we are pleased by the number of key opinion leaders who have supported this process. The innovation funding (NUB) process significantly accelerates the process for obtaining systematic funding for treatment utilising the OncoSil™ device throughout all of Germany. Having experienced the positive uptake of a similar medical device following such classification, it bodes very well for delivering on OncoSil's commercialisation plan."

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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.

The United States Food and Drug Administration (FDA) have granted an Investigational Device Exemption (IDE) 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.