ASX Announcement / Media Release

28 March 2022

Fully-Funded Trial Approved In Germany To Increase Sales of OncoSil™ Device

Key Highlights

- ✓ **The Federal Joint Committee (G-BA) has recommended a fully-funded trial take place in Germany;**
- ✓ **Favourable results from the clinical trial will lead to the OncoSil device being fully-funded for patients in Germany, through public insurance reimbursement;**
- ✓ **OncoSil will receive revenue payments for the provision of the OncoSil™ device used within the clinical trial; and**
- ✓ **The G-BA decision builds on the nationwide momentum in Germany following the NUB Status 1 innovation funding agreed in February 2022 and the subsequent approval of 25 hospitals permitted to negotiate for funding for the OncoSil™ device.**

Sydney, Australia – 28 March 2022: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), a medical device company focused on localised treatments for patients with pancreatic cancer, is pleased to announce that the Federal Joint Committee (G-BA) has approved a fully-funded trial in Germany to assess the OncoSil device compared with Chemotherapy in the treatment of Locally Advanced Pancreatic Cancer (LAPC).

The Federal Joint Committee (G-BA) is the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany.

The assessment of the OncoSil device and the decision to fund a clinical trial will enable OncoSil to enhance the current body of evidence with a comparative trial to compare the combination of standard-of-care (SoC) chemotherapy and OncoSil versus SoC chemotherapy alone, in treating LAPC.

The OncoSil™ device has a CE Mark in Europe and the UK, receiving the Breakthrough Device designation in the US, Europe and the UK. A successful outcome of the G-BA clinical trial would be expected to lead to the approval of public funding for the treatment of patients in Germany with unresectable locally advanced pancreatic cancer. As stated above, OncoSil will also receive additional device sales revenues for the provision of the OncoSil™ device over the course of the clinical trial.

The decision to initiate and fund a clinical trial follows the receipt of a "Positive Status 1" classification under the innovation funding (NUB) program as announced on 3 February 2022. The 25 leading university hospital sites in Germany who had submitted NUB requests will also be able to participate within the clinical trial.

The G-BA decision and the classification under the NUB program is expected to significantly increase the profile of the OncoSil™ device with Key Opinion Leaders and stakeholders in the German market and throughout the EU and UK.

OncoSil's Market Access and Reimbursement group will continue to assess other opportunities for similar fully-funded and revenue generating programs within the EU to augment the clinical evidence base for treating pancreatic cancer and to increaser patient access to the OncoSil™ device.

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

"The G-BA agreeing to fully-fund a clinical trial in Germany, represents a very positive step forward in being able to better commercialise the OncoSil™ device in Germany. Favourable results from this trial will lead to public insurance reimbursement funding of the OncoSil device for all patients in Germany with Locally Advanced Pancreatic Cancer. In particular, the OncoSil™ device offers a promising treatment alternative in a disease of high unmet need. Revenue receipts from the provision of the OncoSil device in the clinical trial will also assist in accelerating revenue growth in Germany and eventually throughout Europe."

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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.

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.