

#### **ASX Announcement**

#### 22 October 2020

# OncoSil achieves first sale in New Zealand and provides European operational update

## **Key Highlights**

- Milestone achievement with first Commercial Sale of OncoSil™ in New Zealand
- Commercial Preparations underway in Europe targeting first revenues in Q4 2020

Sydney, Australia – 22 October 2020: OncoSil Medical Ltd (ASX: OSL) (OncoSil or the Company), is pleased to announce that it has achieved first revenues after its first commercially treated patient was implanted with the OncoSil™ device in New Zealand on 21 October 2020. This is a very significant achievement for OncoSil and marks the Company's transition towards being a revenue-generating medical device company.

OncoSil was able to successfully manufacture, dispense and ship the device system from Germany to New Zealand despite the COVID-19 pandemic. This is a demonstration of our operational capabilities and provides a clear pathway for further first sales in other approved jurisdictions.

#### Commenting on the first sales, OncoSil CEO and Managing Director, Daniel Kenny, said:

"The first sale represents an important milestone for OncoSil as we begin transforming ourselves into a global commercial-stage medical device company. In Europe, our launch preparations continue to progress well with training and other critical activities well underway. We continue to target first sales in Europe later this year and we will continue to work diligently to ensure that this happens."

# European sales update

To facilitate first revenues in Europe by the end of year we have onboarded multiple hospitals throughout Europe and have established a central radio-pharmacy in the UK which will dispense the OncoSil<sup>™</sup> device in up to 15 hospitals in the greater London area. However, the risk of another severe lockdown across Europe as a result of the COVID-19 pandemic remains the greatest unknown factor in our planned launch timeline. The COVID-19 pandemic has slowed launch preparations including site training and certification work. Despite these interruptions, we continue to progress our launch preparations in Europe and remain on track for first revenues in Q4 2020.

To support the recent appointment of Nigel Lange (EMEA President), we have employed 9 new staff into our direct sales and training team across the UK, Germany, Italy and Benelux with a view of growing this further. The additional headcount will help to drive our sales, development and commercialisation goals in the European market.

## **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.