**ASX Announcement**

**1 June 2020**

# OncoSil receives Singapore regulatory approval

**Key Highlights**

- **OncoSil receives regulatory approval from Singapore's Health Sciences Authority (HSA)**
- **OncoSil™ device can now be marketed and sold in Singapore**
- **Expedited approval aided by recent CE marking and the use of the Priority 1 pathway, available to OncoSil as part of being granted breakthrough device designation**
- **Singapore is a strategically important market and marks the beginning of OncoSil's commercialisation in Asia**

**Sydney, Australia – 1 June 2020:** OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), is pleased to announce that it has received regulatory approval from Singapore's Health Sciences Authority (HSA) for its OncoSil™ device. The successful registration means OncoSil is now able to market and sell the OncoSil™ device in Singapore, for the treatment of locally advanced pancreatic cancer.

OncoSil filed for approval in Singapore under Route 1 of the Priority Review Scheme.

Singapore's Health Sciences Authority (HSA) determined in July 2018 that the OncoSil™ device fulfilled the criteria for Route 1.

Route 1 criteria are:

- Key health focus area (cancer)
- No existing alternative OR;
- The device is a breakthrough technology providing an advantage over existing technology

As announced on 4 May 2020, OncoSil filed for registrations in Singapore, Hong Kong and Malaysia following the CE Marking received on 1 April 2020.

**Commenting on the approval, OncoSil CEO and Managing Director, Daniel Kenny, said:**

*"We are pleased to receive the regulatory approval in Singapore as it represents a key step in the company's Asian commercialisation strategy. Although Singapore is a smaller market, it is a significant and attractive market for OncoSil. With the recent CE Mark and now our first Asian approval, OncoSil is taking all the key steps in shifting itself into a commercial-stage medical device company."*

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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.

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 intrahepatic and distal cholangiocarcinoma. 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.