ASX Announcement

18 March 2020

FDA grants Breakthrough Device Designation for the OncoSil™ device for treatment unresectable pancreatic cancer

Key Highlights

- **OncoSil Medical receives FDA Breakthrough Device Designation for its device for the treatment of unresectable locally advanced pancreatic cancer in combination with systemic chemotherapy.**
- **OncoSil™ device represents breakthrough technology and offers significant advantages over existing approved or cleared alternative treatments.**
- **Breakthrough Device Designation will expedite development and approval of the OncoSil™ device in the US.**

Sydney, Australia – 18 March 2020: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**) is pleased to announce that the OncoSil™ device has been granted Breakthrough Device Designation by the FDA for the treatment of unresectable locally advanced pancreatic cancer in combination with systemic chemotherapy. This designation is a significant milestone for the Company as breakthrough designation will expedite development and approval of the device in the US market as defined by the Breakthrough Devices Programme (BDP)

The Breakthrough Devices Program (BDP) is intended to expedite the FDA review and approval of designated devices that may provide more effective treatment of life-threatening or irreversibly debilitating diseases. The BDP is intended to assist patients gain faster access by expediting device development, assessment, and review, while preserving the standards of premarket approval.

The Company will now work closely with the FDA to ensure that the proposed premarket approval (PMA) evidence development and clinical trial design captures clinically meaningful data required in the post market setting. For PMAs designated as breakthrough devices, FDA utilises timely post-market data collection, when appropriate, to facilitate expedited and efficient development and review, potentially shifting some clinical data gathering to the post-market setting, speeding market approval. With the breakthrough designation, OncoSil Medical is well positioned to accelerate its device development plans in the US.

“The granting of Breakthrough Device Designation by FDA of the OncoSil™ device offers the Company many benefits with respect to PMA trial design, device assessment and expedited review” said Daniel Kenny, CEO and Managing Director of OncoSil Medical.

“Breakthrough designation also provides validation of the OncoSil™ device as it represents a novel technology that has the potential to provide clinically meaningful benefits to patients in terms of

increased Overall Survival (OS) and downstaging tumours to resection with curative intent" added Mr Kenny.

US FDA Breakthrough Device Designation

To qualify for FDA Breakthrough Device Designation a Company must demonstrate that its device meets the following criteria:

- Device provides more effective treatment or diagnosis of a life-threatening or irreversibly debilitating disease or condition
- Device represents breakthrough technologies
- No approved or cleared alternative device is currently marketed in the US
- Device offers significant advantages over existing approved or cleared alternatives
- Device availability is in the best interest of patients

About the OncoSil™ device – unique platform technology

OncoSil™ is a first in class medical device comprising Microparticles containing Phosphorus-32 (P-32), a pure beta-emitter radioisotope, implanted directly into a patient's pancreatic tumour via endoscopic ultrasound guidance.

The OncoSil™ device is a unique platform technology that could be utilised for most solid tumour types. Focus to date has been on liver (HCC) and pancreatic cancer and will move shortly into biliary cancers.

CE Mark Update

The Company continues to await the CE Marking decision from BSI.

BSI has confirmed that the CE Marking certification process is in its final phase. The Company remains confident of a positive CE Mark decision and will update the market immediately once this decision is made.

-ENDS-

Authorisation & Additional Information

This announcement was authorised by the Board of Directors of OncoSil 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 encouraging results on tolerability, safety and efficacy. OncoSil™ has CE Mark certification and can now be sold commercially in the European Union and the United Kingdom.

The U.S Food and Drug Administration granted an Investigational Device Exemption (IDE) in July 2016 with approval to conduct a clinical study of the OncoSil™ device. The aim of the study will be to collect safety and effectiveness data required to support a Premarket Approval (PMA) application.

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. 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 $1b.

Hepatocellular carcinoma (HCC) or liver cancer, is the 6th most common cancer in the world with 782,000 new cases diagnosed in 2012. While hepatocellular carcinoma can be treated by surgery or transplantation, the majority of patients with HCC have disease which is too advanced for surgery and their survival ranges from a few months to two or more years. The value of the hepatocellular cancer market is expected to triple in size to $1.4b by 2019.

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.