



ASX / Media Release
8th February, 2017

CE Mark Update

Investor Call to discuss Quarterly Results and Outlook at 9.00am AEDT, 9 February 2017

SYDNEY, 8th February, 2017: OncoSil Medical Limited (ASX: OSL) (OncoSil Medical, the Company), a medical device company focused on localised treatments for patients with pancreatic and liver cancer, is pleased to provide the following update on its CE Mark application for OncoSil™.

Based on information received from BSI, the Company is pleased to advise that CE Certification for the pancreatic cancer indication will now be granted subject to the following conditions:

- Provision of supplemental data from 20 locally advanced pancreatic cancer patients supporting the existing safety and clinical performance data already reviewed, and
- OncoSil Medical agrees to undertake a Post Marketing Clinical Follow-up programme.

The 20 patient supplemental data request from BSI is consistent with the request received from the US FDA prior to granting an Investigational Device Exemption (IDE) in July 2016.

The Company is well positioned to provide the supplemental data from its Global Pancreatic Clinical Study programme. Recently the Company confirmed the participation of 12 centres in the programme with Ethics committee approval for the first centre, Monash Health. The OncoSil team has made progress working with large recruitment centres, and some of the sites included in the trial are top-tier cancer centres, including MD Anderson and Johns Hopkins. The Company's efforts are aimed at maximizing recruitment efficiency.

Based on current recruitment projections and data follow-up requirements the Company expects to provide the supplemental data by the end of Q3 2017.

CE Mark review for the Primary Liver indication (HCC) is ongoing.

OncoSil Chief Executive Officer, Daniel Kenny commented: "After a lengthy and complex review it is clear that the Company is now well on its way to obtaining the CE Mark this year. I am pleased with the progress that the OncoSil team has made over the past 12 months in securing the IDE from the FDA, and the on-boarding of top tier recruitment sites in Australia, UK and the US. OncoSil is well positioned to collect the supplemental data quickly and to finalise our post marketing follow up programme to secure the CE Mark in 2017."

Investor Conference Call

The Company will hold a conference call at **9.00am AEDT on 9th February 2017** to discuss the Company's financial results for the Quarter and the business outlook. The Company's Chief Executive Officer and Managing Director Daniel Kenny, will host the call.

To access the call please use the following details: Conference ID: 957281

Australian Toll Free:	1800 908 299
Australia Local (if dialling from international location):	+61 2 9007 8048
New Zealand Toll Free:	0800 452 795
Hong Kong Toll Free:	800 968 273
Singapore Toll Free:	800 101 2702
China Toll Free:	1080 0140 1776
United Kingdom Toll Free:	0800 051 1453
United States/Canada Toll Free:	1855 624 0077

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Company	Media
Mr Daniel Kenny CEO & Managing Director E: daniel.kenny@oncosil.com.au T: +61 2 9223 3344	Ben Walsh WE Buchan E: bwalsh@buchanwe.com.au M: 0411 520 012

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 (Phosphorous-32), implanted directly into a patient's pancreatic tumours via an endoscopic ultrasound.

Treatment with OncoSil™ is intended to deliver more concentrated and localised beta radiation compared to external beam radiation. OncoSil Medical has conducted four clinical studies with encouraging results on tolerability, safety and efficacy. A CE Mark application to commercially sell OncoSil™ in the European Union (EU) is under review with commercial launch, subject to approval.

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.