



ASX / Media Release  
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## Ethics Approval for OncoPaC Clinical Study

**Sydney, Australia, 2 February 2017:** OncoSil Medical Limited (ASX: OSL) (**OncoSil Medical** or the **Company**) a medical device company focused on localised treatments for patients with pancreatic and liver cancer, is pleased to announce that it has been granted Ethics Approval by Monash Health for its OncoPaC global clinical study program for pancreatic cancer.

This represents a significant milestone in the clinical study process to date. The Ethics Approval at Monash Health will also facilitate ethics approval for other participating study centres Australian-wide (except in Western Australia). This in turn will help expedite the patient recruitment process for the Australian arm of OncoPaC.

The successful grant of Ethics Approval at Monash Health comes after the Company filed its Ethics Committee (HREC) submission in November last year. Monash Health is the largest public health service in Melbourne, and has agreed to be the lead Australian study centre. It provides health care services to more than 1.5 million people. All cancer treatments are provided through the Monash Cancer Centre, one of Victoria's premier cancer facilities.

To date, OncoSil Medical has confirmed the participation of 12 centres for its global pancreatic clinical study program, and is currently in discussions with a further seven centres in the UK, Europe and Australia. The Company will progressively add new centres to its trial program over the coming months, and will also progressively commence patient recruitment globally into the study.

OncoSil Medical will update the market on the progress of the OncoPaC clinical study program in due course.

OncoSil Chief Executive Officer, Daniel Kenny commented:

*"We are extremely pleased to have secured Ethics Approval for our global OncoPaC clinical study program in pancreatic cancer at Monash Health. Monash is a highly regarded cancer centre and is also the lead Australian centre for our clinical study program. With Ethics Approval granted at Monash, it now paves the way for the provision of ethics approvals across other Australian study centres, a pivotal requirement in the study program."*

### Participating Study Centres

The University of Texas, MD Anderson Cancer Centre in Texas, USA – joint lead US study centre

The Johns Hopkins University Hospital, University Medical School in Maryland, USA – joint lead US study centre

The Moffitt Cancer Centre, Tampa, USA

Northwestern Memorial Hospital, Chicago, USA

Cedars-Sinai Hospital, Los Angeles, USA

Guy's and St Thomas' Hospital, UK – lead UK study centre

The Royal Liverpool, UK

Hammersmith Hospital, London, UK

Addenbrookes Hospital, Cambridge, UK

The Institute Jules Bordet, Brussel, Belgium - lead Belgian study centre

Monash Health, Melbourne, Australia - lead Australian study centre, and

St Vincent's Hospital, Sydney, Australia

- ENDS -

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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 (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.