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## **UK Central Ethics Approval for Pancreatic Clinical Study Programme**

## **Highlights**

- UK Central Ethics Approval has been granted for the global pancreatic clinical study programme
- This approval initially for Guys and St Thomas' Hospital London will now facilitate ethics approval for all 5 participating UK study centres
- This approval will expedite patient recruitment for the UK arm of clinical study.
- In Australia, Westmead Hospital was granted Ethics approval on 28 March

**Sydney, Australia, 4 April 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 UK Central Ethics Approval for its global clinical study programme for pancreatic cancer.

The Central Ethics Approval granted on 31 March initially covering Guys and St Thomas' Hospital, London will facilitate ethics approval for all 5 participating centres in the United Kingdom. This in turn will help expedite the patient recruitment process for the UK arm of the clinical study.

The UK centres participating in the global pancreatic clinical study programme are:

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

The University of Leicester

The Royal Liverpool

Hammersmith Hospital, London

Addenbrookes Hospital, Cambridge

In Australia, Westmead Hospital, Sydney was granted ethics approval on 28 March and will over the coming weeks finalise preparation to enrol patients into the study programme.

Westmead Hospital is a specialised tertiary referral hospital for the Western Sydney metropolitan area, serving one of the largest growing population areas in the state of New South Wales.

OncoSil Chief Executive Officer, Daniel Kenny commented:

"We are extremely pleased to have secured Ethics Approval for our global pancreatic clinical study programme in pancreatic cancer at Guys and St Thomas' Hospital in London. The Guys and St Thomas' NHS Trust is a highly regarded cancer centre internationally and is also the lead UK centre for our clinical study programme. The granting of Central Ethics Approval now paves the way for the provision of ethics approval across the other four (4) UK study centres. The granting of ethics approval for Westmead Hospital means that shortly this hospital will join St Vincent's in Sydney and Monash Health in Melbourne in recruiting patients for the clinical programme."

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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.