ASX Announcement / Media Release

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OncoSil provides positive regulatory updates for OncoSil™ device for both EU and the USA

Sydney, Australia – 11 October 2019: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), a medical device company focused on localised treatments for patients with pancreatic and liver cancer, wishes to provides an update on its CE Mark review and positive regulatory developments for the US market.

CE Mark update

OncoSil is pleased to report that the company has completed its follow up meeting with British Standards Institute (BSI) Management and the Clinical Oversight Committee (COC) on October 3rd in London. In the meeting the Company made a comprehensive and detailed presentation addressing all concerns and issues raised in the previous assessment by BSI and the COC.

Providing support to the Company presentation were pre-eminent international experts in medical oncology, radiation oncology and hepato-pancreato-biliary surgery. Also in attendance were leading regulatory specialists providing guidance on process and regulations.

The Company was encouraged with the meeting and the hearing that BSI and the COC provided to the Company. As expected, no formal decision was given at the meeting. A formal assessment report from BSI and the COC should be provided within the coming weeks.

At the conclusion of the meeting BSI requested that the Company submit an updated Clinical Evaluation Report (CER) which includes the clinical data and analysis of the PanCO study results as presented to the COC. OncoSil is now focused on submitting an updated CER for the OncoSil™ device for CE Mark approval.

“The meeting with the Clinical Oversight Committee was positive and has provided a clear path forward for OncoSil. Submitting the CER as quickly as possible remains our immediate focus and we expect to submit in the coming weeks,” said OncoSil CEO Mr Daniel Kenny.

“We would like to acknowledge the support of leading and pre-eminent medical experts who assisted OncoSil in the lead up to this meeting. We look forward to updating the market on the progress of our CE Mark application.”

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US Regulatory Update

The Company has been exploring various US regulatory pathways for its device while we have been awaiting the outcome of its CE Mark application and commercialisation in Europe.

As a part of this process The Company has been exploring a new indication for the OncoSil device and identified an opportunity in the US market for the treatment of cholangiocarcinoma (bile duct cancer). OncoSil believes its brachytherapy device provides a new treatment option for this difficult disease, similar in nature to how it currently targets pancreatic cancer.

The Company has applied for and the US FDA has subsequently granted OncoSil Medical a Humanitarian Use Designation (HUD) for both intrahepatic (ICC) and distal cholangiocarcinoma (dCCA). The HUD program creates an alternative pathway for obtaining market approval for medical devices that may help patients with rare diseases or conditions. A HUD is defined by the FDA as a medical device intended to benefit the treatment or diagnosis of a disease or condition that affects, or is manifested in, not more than 8,000 individuals in the US per year.

In July the Company held a successful Pre Submission meeting with FDA seeking guidance from the agency on a potential future Humanitarian Device Exemption (HDE) submission in dCCA. In written feedback the FDA confirmed the acceptance of a predicate approach whereby clinical data obtained in locally advanced pancreatic cancer could be applied to the treatment of dCCA.

Building upon the success of both the HUD designation and the HDE Pre Submission meeting the Company will apply for a HDE in dCCA for the OncoSil device from the US FDA. The HDE submission will apply the predicate approach utilising the clinical safety and performance data obtained from the PanCO study and the Company expects to have filed this submission within the coming months and will update the market upon submission.

At this time OncoSil Medical plans to focus on dCCA. HDE approval for intrahepatic cholangiocarcinoma (ICC) will be subject to a future separate application.

Mr Kenny noted that the Company is encouraged by recent progress in the US, with a clear pathway to enter into the US now identified.

“Being granted a HUD for both intrahepatic and distal cholangiocarcinoma is a significant milestone for the Company and creates a pathway for US approval for our device to treat a malignancy for which very few treatment options are available”

-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 (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 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.

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.