ASX Announcement / Media Release

28 October 2019

OncoSil submits updated Clinical Evaluation Report to BSI

Sydney, Australia – 28 October 2019: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**) announces it has submitted an updated Clinical Evaluation Report (CER) to the British Standards Institute (BSI) as part of OncoSil™ device's CE Mark certification process.

The updated CER was requested by the BSI as an outcome of the Company's meeting with the Notified Body and its Clinical Oversight Committee on 3 October.

The CER includes the latest clinical data and analysis from the PanCo study, an update systematic literature review (SLR) from a broad range of clinical studies of **systematic chemotherapy (CT-only)** and **induction chemotherapy plus consolidated chemo-radiotherapy (ICT+CCRT)** regimens supported in clinical guidelines as the current "state-of-the-art" treatment for unresectable LAPC

The outcomes from this SLR were compared with the results of the PanCO study in a naïve indirect treatment comparison and statistically analysed.

This analysis confirms that the OncoSil™ device, when combined with contemporary systemic chemotherapy regimens, demonstrates the following:

- The PanCO study met & exceeded its primary safety and clinical performance endpoints. The study results now provide a broad and consistently positive set of outcome measures that underline the clinical benefits that treatment with OncoSil™ provides for patients with unresectable LAPC

- **Local Disease Control Rates at 16 weeks ($LDCR_{16\ weeks}$) of 82% in the Intention-to-Treat (ITT) cohort of enrolled patients (p<0.0001) and 90.5% in the Per Protocol (PP) population (p=0.0001)** that received OncoSil™ plus CT, demonstrate that the PanCO study convincingly met its *a priori* primary performance endpoint. **This convincingly demonstrates that OncoSil™ plus CT is better than CT alone.**

- **Prolonged median overall survival** of 15.5 months in the ITT cohort and **16.0 months in the PP population**. In the naïve indirect treatment comparison, **the PanCO median OS results were significantly longer (*p*<0.001) than CT-only and ICT + CCRT regimens, representing a clinically relevant 20% reduction in the risk of death compared to CT-only and ICT + CCRT studies.**

- **An encouraging rate of surgical resection with curative intent of 23.8%.** Nearly one-in-four PanCO patients were "converted" from an initially inoperable to surgically resectable state when the OncoSil™ device is used in combination with optimum chemotherapy. This **rate is significantly greater than those reported in the CT-only and ICT + CCRT studies (*p*<0.001)** and, notably, the rate of R0 (tumour free) margin status was 80%. Surgical resection of pancreatic cancer,

particularly in patients previously determined to be unresectable, profoundly **improves patients' prognosis from a five-year survival rate of 5% to greater than 20%.**

- **Progression-free survival (PFS)** was also prolonged (9.3 months in the ITT and PP populations), and was **significantly greater than 'state-of-the-art' CT - only and ICT + CCRT studies (*p*<0.001).**

- **Disease control and overall response rates in the PanCO study – 95.7% and 29.8%, respectively, in the ITT group; 100% and 31.0% in the PP population** – underline the response following OncoSil™ administration and were again **significantly greater than the CT - only and ICT + CCRT studies in the naïve indirect treatment comparison.**

- These encouraging results were achieved **despite relatively low CT intensity** (due to dose delays ≥one week, dose reductions and/or termination of CT) which was observed in patients prior to OncoSil™ administration as well as in a similar proportion of the patients who did not receive OncoSil™.

- The primary endpoint of the PanCO study was met, with the results **demonstrating a satisfactory safety profile overall, with no convincing evidence of significant safety concerns or unexpected/serious toxicities associated with the OncoSil™ device and/or implantation procedure over a prolonged study timeframe.**
- The OncoSil™ device provides a valuable treatment option in an area of high unmet medical need with an **acceptable safety and tolerability profile.**

- The clinically relevant benefits of OncoSil™ combined with systemic chemotherapy in appropriate patients with unresectable LAPC more than outweigh the identified risks, and represent a **favourable risk-benefit profile.**

OncoSil Medical considers that all Essential Requirements/Principles of AIMDD and MEDDEV have been met to support CE Mark registration of the OncoSil™ device. The CER was prepared by OncoSil with the support of leading and pre-eminent medical experts.

BSI is expected to review the CER to inform a final determination on OncoSil device's CE Mark approval.

OncoSil CEO Daniel Kenny noted the submission has been a priority for the Company since the clinical review meeting in early October.

"The completion and submission of the updated Clinical Evaluation Report for the OncoSil device has been an immediate focus for the Company following the COC meeting in London on October 3rd" said Mr Kenny.

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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.