ASX Announcement
25 October 2018

Highly Encouraging Interim Analysis for OncoSil's PanCO Study

Investor Call to discuss Interim Analysis, Quarterly Results and Outlook at 9:30 am AEDT, 29 October 2018

Sydney, Australia, 25 October 2018: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), a medical device company focused on localised treatments for patients with pancreatic and liver cancer, is pleased to provide an overview of the recently completed interim analysis from its PanCO study.

Key highlights

Highly encouraging clinical results from an Interim Analysis conducted on OncoSil's PanCO study, with strong clinical performance recorded across multiple metrics:

- **42 patients implanted with the device**
- **Local Disease Control Rate (LDCR) of 88% at Week 16 in the implanted population** (N=42, P<0.0001)
- **Strong evidence of target tumour regression, with statistically significant and in some cases substantial volumetric reduction** (29.7% mean tumour volume reduction by Week 16; maximum reduction 90%; P<0.0001)
- **To date, 9 patients have undergone surgical resection (tumour removal) with curative intent** (21.4% resection rate)
- **8 out of the 9 resections have reported R0 surgical margins.**
- **Interim Analysis has been submitted to BSI as additional evidence of the clinical performance and safety profile of the OncoSil™ device**

OncoSil Chief Executive Director Daniel Kenny commented:

"The results from the PanCO study Interim Analysis are very encouraging. The analysis shows clinically relevant and statistically significant results in numerous important clinical endpoints.

Most notably, the resection data is suggestive of the potential to "convert" selected patients from an initially inoperable status to a surgically resectable and potentially curative state when OncoSil™ is used in combination with chemotherapy.

This finding provides support for future studies of the OncoSil™ device as part of a neoadjuvant treatment strategy in resectable and/or borderline pancreatic cancer."

PanCO Interim Analysis

OncoSil has recently completed an interim analysis on its PanCO study, with 50 patients enrolled and 42 implants completed to date. The key clinical performance and safety findings from this analysis on the OncoSil™ device (when used in combination with standard of care chemotherapy) are very encouraging.

The Interim Analysis compared results using two patient populations for the analysis, namely:

- The Intention-to-Treat population (ITT Population), comprising all 50 patients enrolled regardless of whether they were implanted with the OncoSil™ device or not
- The Per Protocol population comprising all 42 patients enrolled and implanted with the OncoSil™ device (Per Protocol Population)

Key findings from the Interim Analysis are as follows:

- **Local Disease Control Rate (DCR) of 88%** at Week 16 in the Per Protocol (implanted) population (N=42); P<0.0001
- **Strong evidence of target tumour regression**, with statistically significant and in some cases substantial volumetric reduction. (Mean reduction by Week 16 =29.7%, maximum reduction 90%; P<0.0001)
- **Evidence of significant reduction in CA19-9 tumour marker** in Per Protocol (implanted) population from baseline to Week 16 (p=0.0082) with 27% of evaluable patients showing a reduction in CA19-9 in excess of 90%
- **Evidence of significant metabolic response on FDG-PET scanning** in the Per Protocol Population from baseline to Week 12, (Median TLG reduction 60.5%; p=0.0012, Median SUV Max reduction 41%; p=0.0002) with four patients demonstrating complete metabolic response (100% reduction in TLG and SUV Max)
- **Nine patients implanted with OncoSil device were subsequently re-staged and have undergone surgical resection with curative intent** (8 with reported R0 surgical margins, a predictor of improved survival:

  Although not a pre-specified study objective, this is a promising finding and is suggestive of the potential to "convert" selected patients from an initially inoperable to a surgically resectable and potentially curative state when the OncoSil device is used in combination with optimum chemotherapy
- **Evidence of a satisfactory safety profile** overall with no convincing evidence of significant safety concerns or unexpected/serious toxicities associated with the investigational device (OncoSil™)
- **No evidence to suggest significant additional risk** when OncoSil™ is used with contemporary systemic chemotherapy regimens
- **Overall safety profile largely consistent with that expected in a high-risk population receiving chemotherapy**. The acceptability of the current safety profile has been confirmed by the independent Safety Review Committee which has met on four occasions since commencement of the study to scrutinise the accumulating safety dataset.
- **Evidence of the utility of contemporary SPECT-CT Bremsstrahlung imaging for confirming satisfactory localisation of the OncoSil™ implant.**
- **User experience confirms the feasibility, acceptability and tolerability of EUS-directed implantation.**

This compelling data from the Interim Analysis suggests that the OncoSil™ device has a favourable benefit-risk profile when used with standard-of-care chemotherapy in a high risk patient population with unresectable locally advanced pancreatic cancer.

CE Mark application

As previously communicated to the market, the British Standards Institute (BSI), the notified body overseeing the Company's CE Marking application, is currently undertaking the detailed review necessary for granting the CE Marking as is required by the relevant EU laws and regulations. As the OncoSil™ device is an implanted radioactive medical device, BSI requires time to undertake the necessary due diligence of the detailed report submitted by the Company.

In further support of BSI's diligence, the Company has submitted the full PanCo Interim Analysis data as additional evidence of the clinical performance and safety profile of the OncoSil™ device.

The Company is encouraged by the constructive engagement with BSI and will continue to keep the market informed of progress towards CE Mark certification during this process.

Investor Conference Call

The Company will hold an investor conference call at **9:30 am AEDT on 29 October 2018** to discuss the Interim Analysis, 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: 675454

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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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.