ASX/ Media Release
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OncoSil presents positive Overall Survival data at American Society of Oncology (ASCO) Annual Meeting

Sydney, Australia, 4 June 2019: 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, today provided positive Overall Survival data for its PanCo study at the American Society of Clinical Oncology (ASCO) Annual Meeting 2019 in Chicago.

The PanCO study is an ongoing international multi-institutional, single arm study which is being conducted across 12 sites in Australia, UK and Belgium. The study objectives are to further investigate the safety, efficacy, feasibility and performance of the OncoSil™ device when implanted intratumorally in patients with non-resectable locally advanced pancreatic cancer.

Dr Paul Ross of Guy's Hospital, London, and Principal Investigator of the PanCo study gave a poster presentation on the data on behalf of the international PanCo study group.

Key highlights

- **42 patients in the per protocol (implanted) population**
- **Median Overall Survival of 16 months in the per protocol population (implanted)**
- Surgical Resection with curative intent
    - Ten patients underwent surgical resection: 23.8% resection rate
    - R0 surgical margin status confirmed in 8 patients, R1 status in 2 patients
        - While resection rates was not an endpoint of the study, these positive figures suggest 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
- PET Scan Assessments
    - 39/42 patients had evaluable PET scan assessments at Baseline and Week 12
    - 100% Metabolic resolution and absence of neoplastic disease in 5 patients at Week 12, 4 have undergone surgical resection
- CA 19-9 Tumour Marker
    - 11/38 patients (29%) demonstrated **a decrease in CA19-9 of > 90%**
- **Local Disease Control Rate (LDCR) at 16 weeks of 90.5% (N=42, P<0.0001),** a positive and important independent prognostic factor for the OS of patients
- **A satisfactory safety profile when OncoSil is combined with contemporary chemotherapy**
- **Confirmation of the feasibility of EUS directed implantation**

Commentary

Non-resectable LAPC is a malignancy with poor prognosis and is remains an area of significant unmet medical need, accounting for 30-40 per cent of all pancreatic cancer presentations[1].

[1] Ariake K, et al. Surg Case Rep 2017; 3:15

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The PanCo study showed promising survival estimates with **median overall survival of 16 months.**

The accepted population median overall survival estimates of patients with locally advanced pancreatic cancer is **only 9-11 months**[2]

The result is comparable to and in many cases surpasses that of the best available published literature in the locally advanced pancreatic cancer population.

Overall survival is universally recognized as being unambiguous, unbiased, an endpoint of paramount clinical relevance, and a positive result provides confirmatory evidence that treatment extends the life of a patient.

"An improvement in overall survival that surpasses the best available published literature for non resectable local advanced pancreatic cancer patients demonstrates an unequivocal direct clinical benefit for patients. These data along with other clinically and statistically relevant outcome measures already documented from the PanCO study will be discussed with BSI and the Clinical Oversight Committee following the ASCO presentation. " said CEO Daniel Kenny

Poster Presentation

- Abstract: PanCO: An open-label, single-arm pilot study of phosphorus-32 (P-32; Oncosil) microparticles in patients with unresectable locally advanced pancreatic adenocarcinoma (LAPC) in combination with FOLFIRINOX or gemcitabine + nab-paclitaxel (GNP) chemotherapies.
- Presenter: Paul J. Ross, PhD, FRCP, Guy's Hospital, London, and Principal Investigator of the PanCo study

A copy of the poster presentation is available on the Oncosil website.

- ENDS -

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[2] Loehrer PJ et al. J Clin Oncol 2011 Nov 1;29 (31) 4105-12

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.