ASX Announcement

24 December 2021

PanCO Clinical Study on OncoSil™ Published in *ESMO Open*

International, Multi-Centre Study shows Encouraging Safety and Efficacy Results for OncoSil™ Added to Standard-of-Care Chemotherapy for Patients with Unresectable Locally Advanced Pancreatic Cancer

Key Highlights

- **Addition of OncoSil™ radioactive microparticles to standard-of-care chemotherapy is safe and effective;**
- **Local disease control at 16 weeks achieved in 90.5% of the patients treated; and**
- **23.8% of patients proceeded to surgical resection with curative intent.**

Sydney, Australia – 24 December 2021: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**) is pleased to announce the publication of the final results of the PanCO clinical study. The results demonstrate the safety and efficacy benefits of the OncoSil™ device in combination with standard-of-care chemotherapy for the treatment of patients with unresectable locally advanced pancreatic cancer (LAPC). The full paper is published in *ESMO Open*, the European Society for Medical Oncology's peer-reviewed open-access journal dedicated to publishing high-quality medical research.

PanCO was an international, multi-centre, single-arm, prospective clinical study of intra-tumoral OncoSil™ phosphorus-32 microparticles for unresectable LAPC. It was conducted at 10 specialist centres in Australia, Belgium and the United Kingdom.

The primary endpoint of the PanCO study was safety and tolerability, and the results demonstrated that OncoSil™ had an acceptable safety profile when added to standard-of-care chemotherapy comprising either gemcitabine plus nab-paclitaxel or FOLFIRINOX, the two most widely used regimens for treating patients with advanced pancreatic cancer. No radiation-related serious Adverse Events (AEs) were reported in the PanCO study and there was no evidence that the incidence of severe AEs changed after OncoSil™ implantation.

The main efficacy endpoint of the PanCO study was the proportion of participants with local disease control at 16 weeks, which was achieved in 90.5% of the patients. This met the pre-defined criteria for statistical significance ($p<0.0001$). In thirteen (31.0%) of the PanCO study participants who received OncoSil™, partial responses to treatment were demonstrated with a disease control rate of 100% as the best response.

Although the study recruited patients whose cancers were defined as unresectable by highly experienced pancreatic cancer experts, nearly one-in-four of the PanCO study participants (10 of 42; 23.8%) proceeded to surgical resection with curative intent following treatment with chemotherapy plus OncoSil™. Furthermore, there were additional patients who received chemotherapy plus OncoSil™ who also became technically resectable, but they did not proceed to surgery for medical reasons or patient choice.

Compared to baseline, there were statistically significant reductions in the volume of the target tumour for study participants (median reduction was 51.9%), as well as in blood biomarkers of the cancer (CA 19-9 decreased by 82.3% on average). The metabolic activity of participants' tumours was assessed at 12 weeks by positron emission tomography (PET) imaging, which also showed significant reductions from baseline. Five patients who received OncoSil™ showed a complete (100%) metabolic response.

The median progression-free survival (PFS) of PanCO study participants who received chemotherapy plus OncoSil™ was 9.3 months and local PFS was 9.8 months. The median overall survival was 15.5 months.

Dr Paul Ross, Consultant Medical Oncologist at Guy's & St Thomas' Hospital NHS Foundation Trust, London, UK, who was principal investigator of the PanCO study said:

"The results of this important clinical study provide evidence that OncoSil™ can address a significant unmet clinical need in patients with unresectable locally advanced pancreatic cancer. The results clearly show an acceptable safety profile and encouraging clinical benefits for patients."

OncoSil's CEO and Managing Director, Mr Nigel Lange said:

"We are very encouraged by the published results of the PanCO study, which is a significant addition to the accumulating clinical evidence to support the use of the OncoSil™ device for the treatment of patients with unresectable locally advanced pancreatic cancer. We will be sharing this clinical evidence with gastroenterologists, oncologists and nuclear medicine physicians to make this novel treatment more widely available to patients."

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Reference

Ross PJ, Wasan HS, Croagh D, Nikfarjam M, Nguyen N, Aghmesheh M, Nagrial AM, Bartholomeusz D, Hendlisz A, Ajithkumar T, Iwuji C, Wilson NE, Turner DM, James DC, Young E and Harris MT. Results of a single-arm pilot study of ^{32}P microparticles in unresectable locally advanced pancreatic adenocarcinoma with gemcitabine/nab-paclitaxel or FOLFIRINOX chemotherapy. ESMO Open February 2022; 7 (1): 100356. https://www.sciencedirect.com/science/article/pii/S2059702921003185

Authorisation & Additional Information

This announcement was authorised by the Board of Directors of OncoSil Medical Limited.

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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 six clinical studies with positive results on tolerability, safety and efficacy. CE Marking has been granted for the OncoSil™ device which can be marketed in the European Union and the United Kingdom. The OncoSil™ device has also been classified a Breakthrough Device in the European Union and the United Kingdom.

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.

In December 2018, the FDA granted Humanitarian Use Designation (HUD) for the OncoSil™ device for the treatment of unresectable bile duct cancer. In March 2020, the FDA granted Breakthrough Device Designation for the OncoSil™ for unresectable pancreatic cancer in conjunction with systemic chemotherapy.

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 $3b.

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.