ASX Announcement

30 June 2023

First Multi-Centre Data on OncoSil™ in Metastatic Pancreatic Cancer presented at ESMO World Congress on Gastrointestinal Cancer (WCGIC)

Key Highlights

- ✓ **First multi-centre data on OncoSil™ with chemotherapy in treating patients with metastatic pancreatic cancer;**
- ✓ **Metastatic pancreatic cancer is outside the current CE Mark and other regulatory approvals on the use of OncoSil™;**
- ✓ **OncoSil™ implantation into the primary pancreatic tumour was safe and feasible for patients with metastatic pancreatic cancer receiving systemic chemotherapy;**
- ✓ **The study reported encouraging clinical outcomes including a 100% Local Disease Control Rate (LDCR) at 3 months after implantation and a median overall survival of 13.9 months from commencement of chemotherapy;**
- ✓ **The results highlight the potential clinical benefits particularly of local tumour control and overall survival in a metastatic pancreatic cancer population in whom outcomes are often poor.**

Barcelona, Spain, 30 June 2023: OncoSil Medical Limited (ASX: OSL) (**OncoSil** or the **Company**) is pleased to announce that the first multi-centre data on the use of OncoSil™ in the treatment of patients with metastatic pancreatic cancer was presented at the European Society for Medical Oncology (ESMO) World Congress on Gastrointestinal Cancer (WCGIC) meeting on 29 June 2023 (after close of trade on ASX).[1]

The study was a retrospective analysis of 14 patients with metastatic pancreatic cancer from 5 centres in Australia and the United Kingdom treated using OncoSil™ in addition to standard-of-care systemic chemotherapy comprising either gemcitabine + nab-paclitaxel (10 patients) or FOLFIRINOX (4 patients). The lead investigator for the analysis was Dr Amanda Lim from the Royal Adelaide Hospital, Adelaide, Australia, and the presenting co-author was Dr Harpreet Wasan from the Imperial College Healthcare NHS Trust, London, United Kingdom. OncoSil™ implantation into the primary pancreatic tumour was safe and feasible for patients with metastatic pancreatic cancer receiving systemic chemotherapy and resulted in encouraging clinical outcomes. The 100% Local Disease Control Rate (LDCR) at 3 months after implantation was 100%, with a significant decrease in the primary tumour longest diameter at both 3 and 6 months from OncoSil™ implantation. When the cancer first progressed in these patients, it was most frequently at a distant site (12 patients; 85.7%) as opposed to local to the primary tumour (5 patients; 35.7%); in 4 patients (28.6%), progression occurred at distant and local sites at the same time. Only 2 patients with distant progression later developed local progression. The median progression-free survival (PFS), both overall and for distant disease, was 5.6 months from implantation, whereas median PFS for local disease was 9.4 months. The median overall survival from commencement of chemotherapy was 13.9 months.

The median overall survival in the pivotal Phase III randomised controlled trials for patients with metastatic pancreatic cancer treated using gemcitabine + nab-paclitaxel was 8.5 months (versus 6.7 months for gemcitabine alone) and treated with FOLFIRINOX was 11.1 months (versus 6.8 months for gemcitabine alone).[2,3]

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

"This is the first multi-centre study of OncoSil™ added to chemotherapy in treating patients with metastatic pancreatic cancer and we are very encouraged by the results reported. It is important to note that metastatic pancreatic cancer is outside the current CE Mark and other regulatory approvals on the use of OncoSil™. However, the results highlight the potential clinical benefits, particularly of local tumour control and overall survival in a metastatic cohort in whom outcomes are often poor."

-ENDS-

References:

1. Lim A, Singhal N, Bartholomeusz D et al. Outcomes of phosphorus-32 (^{32}P) microparticle intra-tumoural implantation added to chemotherapy in patients with metastatic pancreatic adenocarcinoma. Presented at ESMO World Congress on Gastrointestinal Cancer (WCGIC) meeting, 28 June to 1 July 2023; Abstract P-353.
2. Conroy T, Desseigne F, Ychou M et al. FOLFIRINOX versus gemcitabine for metastatic pancreatic cancer. New England Journal of Medicine 2011; 364: 1817–1825.
3. Von Hoff DD, Ervin T, Arena FP et al. Increased survival in pancreatic cancer with nab-paclitaxel plus gemcitabine. New England Journal of Medicine 2013; 369: 1691–1703.

Authorisation & Additional Information

This announcement was authorised by Brian Leedman, Non-Executive Director 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.