ASX Announcement

20 October 2020

Positive PanCO trial update on resected cohort following treatment with Oncosil™

Key Highlights

- **As reported, 42 patients with unresectable, locally advanced pancreatic cancer (uLAPC) enrolled in the PanCO trial in 2017. Typically such inoperable patients have median survival of ~8.5 months[1]**
- **Following treatment, 10 patients (23.8%) underwent surgical resection (removal of tumour), while another 4 were technically eligible for surgery but were unable to undergo surgery due to co-morbidities and/or other considerations.**
- **A sub-group analysis has now been completed on the 10 resected patients, with compelling results:**
  - **Median follow-up of 31.1 months**
  - **60% of resected patients remain alive today with a survival range of 26-35 months post enrolment**
- **Treatment with Oncosil™ has the potential to 'convert' patients from an initially inoperable to a surgically operable state and thus offers a potentially curative outcome with prolonged survival.**

Sydney, Australia – 20 October 2020: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), is pleased to provide an update regarding the resected cohort of patients enrolled in the PanCO trial. As part of the trial, 42 patients with unresectable, locally advanced pancreatic cancer (uLAPC), all initially determined to be inoperable or medically unfit for surgery, were successfully implanted with the OncoSil™ device.

The trial has produced some positive results to date and as previously reported, 10 out of 42 patients (23.8%) were able to undergo surgery with curative intent. Following treatment, 80% of this group demonstrated microscopically negative margins (R0), facilitating surgical intervention and clean resection. In addition, another 4 patients were assessed as being subsequently eligible for surgery post treatment with OncoSil™, however these were unable to undergo surgery due to co-morbidities and/or other considerations. These results imply a technical resection rate of 33%, which is a significant result as the five-year survival rate for pancreatic cancer is ~5%, which can be improved to >20% for those having a surgical resection.[2]

As part of the trial, it is important to confirm the prolonged survival outcomes of the 10 patients that were initially inoperable but now form the resected cohort. OncoSil is pleased to announce that it has completed an updated analysis (data cut off July 2020) and the results are outlined below:

- Median cohort follow-up of 31.1 months:
  - 4 deaths have been reported to date (at 18.8, 20.9, 21.0 and 22.1 months)
  - 6 patients remain alive with a survival range of 26.4-35.3 months post enrolment

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Whilst we continue to monitor the surviving PanCO study patients who have been surgically resected with curative intent, these findings suggest survival that is at least in line with patients receiving neoadjuvant chemotherapy prior to surgical resection for LAPC. This promising finding in the PanCO study also highlights the clear potential to 'convert' patients from an initially inoperable to a surgically operable and potentially curative state when the OncoSil™ device is used in combination with current standard-of-care chemotherapy.

This is a positive outcome and OncoSil will subsequently extend the analysis and provide an update as part of the next follow-up.

Commenting on the results, OncoSil CEO and Managing Director, Daniel Kenny, said:

"The prognosis in patients with unresectable locally advanced pancreatic cancer is extremely poor, with a median overall survival rate of 8.5 months. As reported previously, out of the 42 patients in the PanCO trial, 10 have undergone surgical resection following treatment with the Oncosil device.

We have continued to monitor these patients who were "converted" from inoperable to operable and today I am pleased to report that we have seen a very positive result.

Although the median survival has not yet been reached for the PanCO study participants that underwent surgery with curative intent, the median follow-up of 31.1 months suggests that the survival of this cohort could be expected to be in line with other LAPC patients undergoing surgery and it highlights the significance of our device's ability to prolong survival outcomes through its ability to "convert" previously deemed inoperable patients to an operable status."

[1] Loehrer PJ et al. J Clin Oncol 2011 Nov 1;29 (31) 4105-12
[2] Hartwig W, Werner J, Jäger D, Debus J, Büchler MW. Improvement of surgical results for pancreatic cancer. Lancet Oncol 2013; 14: e476–85.

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.