ASX Announcement

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Comparative Analysis Reports Superiority of OncoSil™ Over Stereotactic Body Radiation Therapy in Patients with Pancreatic Cancer

Sydney, Australia – 7 May 2025: Pancreatic cancer treatment device company **OncoSil Medical Limited (ASX:OSL)** ("**OncoSil**" or "**the Company**") is pleased to announce the results of the first comparative analysis of outcomes in patients with unresectable or borderline-resectable locally advanced pancreatic cancer (LAPC) receiving either OncoSil™ or Stereotactic Body Radiation Therapy (SBRT) in addition to chemotherapy. The analysis is the first comparison of these two different forms of radiotherapy and the results demonstrate the superiority of OncoSil™ in extending overall survival, progression-free survival (PFS) and the rate of downstaging and surgical resection, among other outcomes.

The retrospective, investigator-initiated analysis examined outcomes in more than 100 patients with LAPC treated over an eight-year period at the Royal Adelaide Hospital, South Australia: 42 patients received OncoSil™ plus chemotherapy *vs*. 59 patients received induction chemotherapy followed by SBRT between March 2015 and August 2023. The two cohorts of patients were statistically similar in terms of their age, sex, performance status, burden of pancreatic cancer and chemotherapy regimen used.

The results demonstrate a significantly prolonged overall survival in patients treated with OncoSil™ (median survival: 22 months for OncoSil™ *vs*. 14 months for SBRT; Hazard Ratio [HR] for SBRT: 1.98; p=0.004), as well as significantly longer local and distant PFS (HR: 1.61; p=0.034, and HR: 1.71; p=0.019, respectively). The rate of downstaging was significantly greater in patients treated with OncoSil™ compared to SBRT (24% *vs*. 4.7%; p<0.001), as was the proportion of patients undergoing surgical resection (22% *vs*. 0%; p<0.001).

The frequency of adverse events (AEs) reported was similar in both cohorts, although numerically lower in patients treated with OncoSil™ (grade 3 AEs 0% with OncoSil™ *vs*. 7.3% with SBRT; p=0.098; no grade 4 or 5 AEs in either cohort).

The analysis was performed by investigators at the Royal Adelaide Hospital, South Australia, and presented at the Digestive Disease Week (DDW2025) scientific meeting in San Diego, USA, 3–6 May 2025, by Dr Amanda Lim, an advanced endoscopy fellow at Beth Israel Deaconess Medical Centre in Boston, MA, USA, and an academic researcher from RAH.

The analysis marks another significant milestone for OncoSil Medical, as the presentation provided the first comparative study of OncoSil™ *vs*. SBRT, which is widely regarded as the most targeted form of external beam radiation therapy, in patients with LAPC receiving standard-of-care chemotherapy.

OncoSil Medical Managing Director & CEO Nigel Lange said: *"The results of this important analysis highlight the superiority of the OncoSil™ device compared to Stereotactic Body Radiation Therapy, which is considered to be the best available system for delivering external beam radiotherapy to patients with locally advanced pancreatic cancer. This is also the first study to report on the outcomes following OncoSil™ in a broad cohort of patients that had either unresectable or borderline-resectable LAPC, indicating the potential for OncoSil™ treating patients with earlier stages of pancreatic cancer. These data provide further evidence of the efficacy and safety of OncoSil™ added to standard-of-care chemotherapy."*

A summary of the study is available here

https://eposters.ddw.org/ddw/2025/ddw-2025/4156656/amanda.lim.comparison.of.combined.chemotherapy.and.stereotactic.body.radiation.html?f=listing%3D0%2Abrowseby%3D8%2Asortby%3D1%2Asearch%3Dpancreatic+cancer

Authorisation & Additional Information

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

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About OncoSil Medical

OncoSil Medical Limited (ASX:OSL) has developed a cancer treatment device, the OncoSil™ brachytherapy device, which is a critical component of a revolutionary brachytherapy treatment for locally advanced unresectable pancreatic cancer. This type of cancer is the 12th most common cancer in men and the 11th most common cancer in women across the globe, with some 500,000 new cases of pancreatic cancer detected every year. With pancreatic cancer typically diagnosed at a later stage, it has a poor prognosis for long-term survival[1].

The OncoSil™ device delivers a targeted intratumoural placement of Phosphorous-32 (32P) in the treatment of locally advanced unresectable pancreatic cancer. This occurs via injection directly into a patient's pancreatic tumours under endoscopic ultrasound guidance and takes place in combination with gemcitabine-based chemotherapy.

The OncoSil™ device that has already received breakthrough device designation in the European Union, United Kingdom and United States for the treatment of locally advanced unresectable pancreatic cancer in combination with chemotherapy. CE Marking has additionally been granted for the OncoSil™ device, which can be marketed in the European Union, United Kingdom.

While clinical trials involving the OncoSil™ device continue to occur, the Company is simultaneously moving to commercialise this unique medical technology. It is currently approved for sale in 30+ countries including European Union, United Kingdom, Türkiye and Israel, with initial commercial pancreatic cancer treatments using the device already undertaken in Spain, Italy and Israel.

To learn more, please visit: www.oncosil.com/

References: 1. https://www.wcrf.org/cancer-trends/pancreatic-cancer-statistics/