

ASX Announcement

3 May 2023

First patient enrolled in the TRIPP-FFX Clinical Study

Key Highlights

- ✓ First patient enrolled in the TRIPP-FFX Clinical Study;
- ✓ A total of 80 patients will be recruited, with treatment using the OncoSil™ device being randomised on a 1:1 basis;
- ✓ Primary endpoints include Safety and Tolerability and Local Disease Control Rates at 16 weeks; *and*
- ✓ This study will be used to expand the CE Marking approval of the OncoSil™ device in the UK and the European Union for patients being treated either with gemcitabine-based chemotherapy or FOLFIRINOX chemotherapy.

Sydney, Australia – 3 May 2023: The Board of OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), a medical device company focused on treatments for patients with locally advanced pancreatic cancer (LAPC), is pleased to announce that the first patient has been enrolled in the TRIPP-FFX Clinical Study.

The TRIPP-FFX Clinical Study is an open-label, multi-centre, randomized study of **TaRgeted Intratumoural Placement of Phosphorous-32** (OncoSil™) in addition to **FOLFIRINOX** chemotherapy versus FOLFIRINOX chemotherapy alone in patients with unresectable locally advanced pancreatic cancer. The aim of this Clinical Study is to expand the CE Marking approved use of the OncoSil™ device in the UK and the European Union for patients being treated either with gemcitabine-based chemotherapy or FOLFIRINOX chemotherapy.

The objective of the TRIPP-FFX Clinical Study is to evaluate the safety and efficacy of OncoSil™ in patients with unresectable Locally Advanced Pancreatic Cancer who are treated with FOLFIRINOX chemotherapy.

The primary endpoints of the study include safety and tolerability and Local Disease Control Rate at 16 weeks. Secondary endpoints will also be included in the study, including Overall Survival (OS), quality of life, pain scores, tumour response and surgical resection rates.

The Clinical Study will be conducted in approximately 15 hospital sites in the United Kingdom and the European Union. The total number of patients in the Clinical Study will be 80 patients, randomised on a 1:1 basis for treatment with the OncoSil™ device in addition to chemotherapy versus chemotherapy alone.

A total of four sites have been initiated and are now currently screening patients for the Clinical Study, in key treatment centres in Belgium and Spain.

The first patient has been enrolled in the Clinical Study at the Clínica Universidad de Navarra, Spain.

The Principal Investigator at Clínica Universidad de Navarra, Dr Mariano Ponz Sarvisé said:

“I am very pleased that the TRIPP-FFX study now started enrolling patients. The study will provide researchers and physicians important information on the added value of the OncoSil™ device for patients with LAPC, when used in addition to FOLFIRINOX chemotherapy. This is an important step in the search for new efficacious treatments for patients with LAPC with otherwise limited treatment options.”

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

“We are excited that the TRIPP FFX study has commenced recruitment. The study represents an important milestone in the evolution of the OncoSil™ device as it serves to open the indication thereby making it accessible to a larger patient population diagnosed with LAPC. We look forward to further study sites opening up to recruitment.”

-ENDS-

Authorisation & Additional Information

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

Mr Nigel Lange CEO & Managing Director E: nigel.lange@oncosil.com T: +49 16096424981	Mr Brian Leedman Non-executive Director E: brian.leedman@oncosil.com T: +61 (0) 412 281 780	Mr Karl Pechmann CFO & Company Secretary E: karl.pechmann@oncosil.com T: +61 2 9223 3344
---	--	---

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.