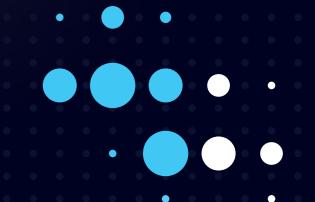


# **Targeted Approach • Positive Impact**

Intratumoural placement of <sup>32</sup>P for locally advanced pancreatic cancer



# We believe our technology will have a truly positive impact in oncology.

OncoSil Medical is a global medical device company focused on Interventional Oncology.

Our mission is to improve the outcomes for people living with cancer by utilising the selected and targeted intratumoural placement of Phosphorous-32 (<sup>32</sup>P) Microparticles in combination with chemotherapy.<sup>1</sup>

OncoSil<sup>™</sup> is our brachytherapy device. Its targeted approach enables healthcare professionals to deliver a greater radiation dose directly into the tumour compared to external beam radiotherapy, while sparing surrounding critical organs.<sup>2</sup>

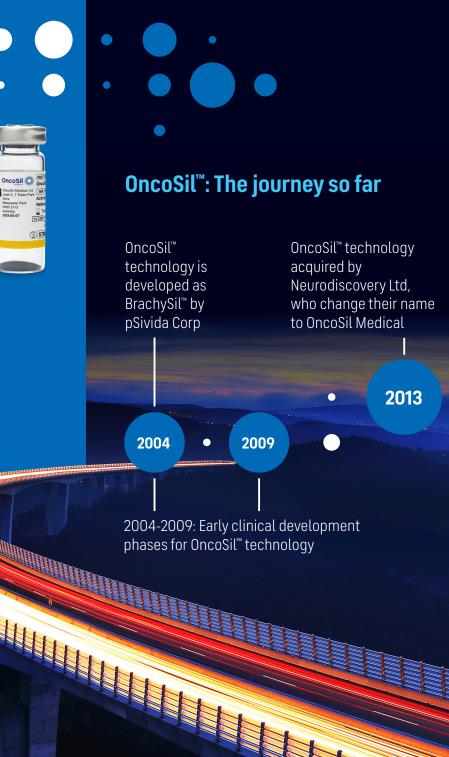
## Targeted approach. Positive impact.

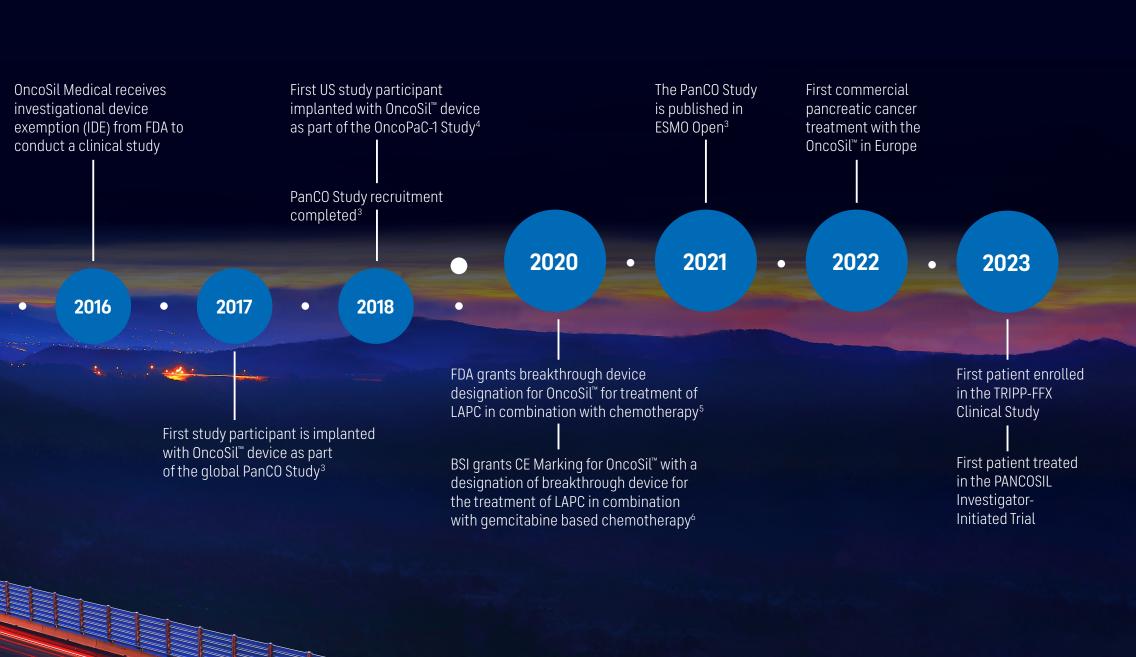
OncoSil<sup>™</sup> enables the TaRgeted Intratumoural Placement of Phosporous-32 (<sup>32</sup>P) or TRIPP, a single, minimally invasive procedure used in combination with chemotherapy<sup>1</sup> for the treatment of locally advanced pancreatic cancer (LAPC).

### OncoSil<sup>™</sup> device treatment pathway\*

CHEMOTHERAPY<sup>1</sup> CONTINUATION OF CHEMOTHERAPY<sup>1</sup> ONCOSIL<sup>®</sup> IMPLANTATION

\*The above diagram is a treatment pathway recommendation only and is intended to provide guidance on the normal course of patient management when considering the use of OncoSil<sup>®</sup> for the treatment of unresectable locally advanced pancreatic cancer in combination with chemotherapy! Chemotherapy should not be administered within 48 hours either side of the OncoSil<sup>®</sup> implantation.





# **Targeted** approach

During the TRIPP procedure, OncoSil<sup>™</sup> is administered directly into the pancreatic tumour via endoscopic ultrasound (EUS) guidance – an approach which offers:



Maximised dose to tumour – 98% of radiation from one fraction delivered over 81 days



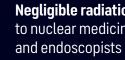
(Per Protocol [PP] Cohort)<sup>3</sup>

Acceptable side-effect profile - well tolerated by patients

 no evidence of additional risk from combining OncoSil<sup>™</sup> with contemporary systemic chemotherapy regimens<sup>3</sup>



Targeted radiation delivery to tumour **protects** surrounding organs<sup>2</sup>



Negligible radiation risk to nuclear medicine staff

# **Positive impact**

The results from the PanCO clinical study demonstrate the benefits of incorporating OncoSil<sup>™</sup> into the treatment strategy for patients with unresectable LAPC.<sup>3</sup>

**High rates** of resection

Downstaging to eligibility for

resection with curative intent

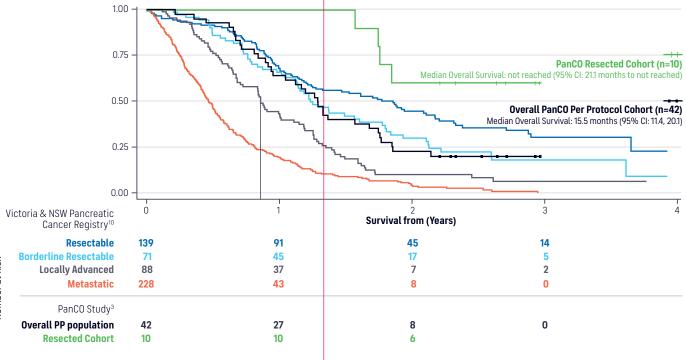
33% **Patients** 14/42

was reached in 33% of patients. Resection was achieved in almost **1 in 4** patients.

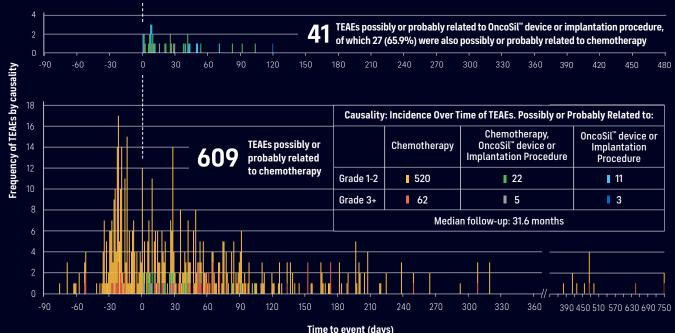


### Survival of PanCO Study vs. Victoria & NSW (Australia) Pancreatic Cancer Registry<sup>3,10</sup> Survival Estimates by Resectability in Treated Group (from Diagnosis, 2016-2019)

Comparison vs. PanCO Cohorts (from Study Enrolment, 2017-2018)



Time to event adjusted to day of OncoSil<sup>™</sup> implantation = Day O



**Incidence of Treatment-Emergent Adverse Events (TEAEs) over Time by Causality** 

15.5

## Favourable surgical margins



8 out of 10 of those patients who were resected had RO surgical margins. Patients for whom RO margins are achieved have been shown to have improved

survival outcomes vs. those with R1 margins.<sup>78</sup>

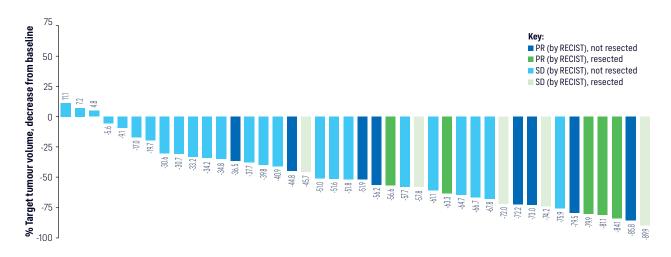
#### **Prolonged median** overall survival

Months Patients treated with OncoSil<sup>™</sup> in combination with chemotherapy<sup>1</sup> experienced a 20% reduction in risk of death\* and median overall survival of 15.5 months

\* When compared to CT-only and ICT/CCRT studies<sup>9</sup>

### Maximum Change in Tumour Volume from Baseline by Outcome<sup>3</sup> **PP Cohort Prior to Surgical Resection**

Tumour Volume, Evaluable Patients	ITT Population, n (%) (N=47/50)	PP Population, n (%) (N=42/42)
Median (range) maximal decrease, %	-51.6% (+72.2% to -89.9%)	-51.9% (+11.1% to -89.9%)
Mean (std dev) maximal decrease, %	-44.0% (34.8)	-49.1% (26.4)
p-value	p<0.0001	p<0.0001



# **Technical overview**

OncoSil<sup>™</sup> is a single-patient, single-use brachytherapy device, comprising Phosphorous-32 (<sup>32</sup>P) Microparticles suspended in a specially formulated Diluent. The Microparticles are a permanent implant which contain Phosphorous-32 (<sup>32</sup>P), a pure beta-emitter radioisotope.



### **Technical specifications**

- Physical half-life: 14.27 days
- Absorbed dose: In therapeutic use, 98% of the radiation is delivered within 81 days, giving an absorbed dose equivalent to 100 Gy<sup>10</sup>
- **Final radioactive concentration: 6.6 Mbq/mL** (following predefined suspension preparation protocol)
- Storage: Room temperature. Do not freeze the Diluent
- Shelf life: 24 hours from the time of dose preparation
- Endoscope flush: Simple saline flush minimises the risk of endoscope contamination

# Simple and flexible preparation and dosing

OncoSil<sup>™</sup> has been specifically developed to offer:

24-hour shelf life to enable pre-planning and aid workplace efficiency

(24)

Flexibility in treatment planning due to a wide 10-day treatment window

Confidence in achieving a total dose to tumour of 100 Gy, delivered over the 81-day time period of sustained OncoSil<sup>™</sup> activity

Day of Implantation Relative to Reference Date	Vial Total Radioactivity MBq
-2	276
-1	262
0	250
+1	238
+2	227
+3	216
+4	206
+5	196
+6	187
+7	178

ay of implantation with associated total vial radioactivity in MBq

#### Treatment

**Generally, an OncoSil<sup>™</sup> implantation is an outpatient procedure.** However, the treating clinicians responsible for the patient's care should determine if admission is required.

### **Certification: Treatment facilities and personnel**

The OncoSil<sup>™</sup> System is to be used in a licensed treatment facility. These facilities must hold an appropriate license for the isotope Phosphorous-32 (<sup>32</sup>P), which mandates that these institutions will have an appointed Radiation Safety Officer (RSO)/Radiation Protection Officer (RPO) who will be the primary contact for all matters related to radiation safety.

The OncoSil<sup>™</sup> suspension should be prepared within the Nuclear Medicine Department or within a licensed Radiopharmacy. Only appropriately licensed personnel, who have been trained in the preparation of the OncoSil<sup>™</sup> suspension may prepare the product for implantation.

#### Intended use/Indications for use:

The OncoSil<sup>®</sup> System is intended to induce prolonged local tumour control and tumour size reduction in patients with locally advanced unresectable pancreatic cancer, in addition to gemcitabine-based chemotherapy, by implantation of radioactive Phosphorous-32 Microparticles into pancreatic tumours under endoscopic ultrasound guidance. OncoSil<sup>®</sup> is indicated for the treatment of patients with locally advanced unresectable pancreatic cancer, in addition to gemcitabine-based chemotherapy.

			viations:															
		BSI:	British Standards Institution		NSW:	New	/ South Wale	es										
		CR:	Complete Response		PP:	Per	Protocol											
			Endoscopic Ultrasound				ial Respons							$\bullet$				
		FDA:	Food and Drug Administration		SAE:	Seri	ous Adverse	e Event										
			Intention to Treat		SD:	Stat	ole Disease											
		LAPC:	Locally Advanced Pancreatic Cano	cer	TEAE:	Trea	itment-Eme	rgent A	Advers	se Eve	nt							
		NC:	Not Calculable		TRIPP	: TaRo	geted Intrat	umour	al Plac	cemer	nt							
						of P	hosporous-3	32 ( <sup>32</sup> P)										



**Targeted Approach • Positive Impact** 

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- 4. OncoPaC-1. ClinicalTrials.gov Identifier: NCTO3076216.
- 5. US Food and Drug Administration (FDA) breakthrough device designation for use in combination with systemic chemotherapy.
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- 10. Croagh D. Presented at the E-AHPBA Congress, Sept 2021. Symposium 'Downstaging Unresectable LAPC. Discussion on the Resection Data from the PanCO Study'.

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