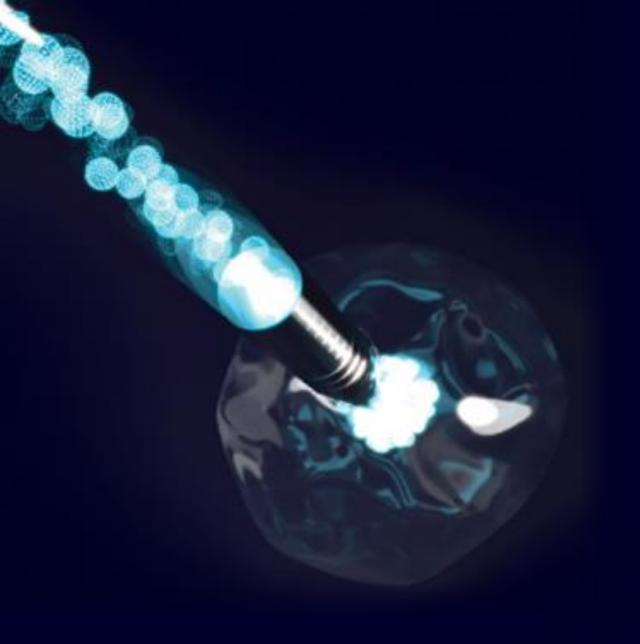


# **CEO AGM Presentation**

19 October 2021

**Targeted Approach • Positive Impact** 





OncoSil Medical's targeted approach will deliver a positive impact in the treatment of pancreatic cancer, aimed at extending the length and quality of life for patients

## OncoSil<sup>™</sup> Device

### **Overview**

OncoSil<sup>™</sup> is intended for the treatment of **locally advanced unresectable pancreatic cancer**, in combination with gemcitabine-based chemotherapy.

OncoSil<sup>™</sup> is implanted directly into a pancreatic tumour via injection under endoscopic ultrasound guidance. OncoSil<sup>™</sup> is a single-use brachytherapy device comprised of microparticles and a diluent.



98% of all radiation is delivered within 81 injection...

...causing direct damage to cancer cell DNA, and ultimately shrinking tumour masses when the cells die.

## Management Team with a Depth of Experience and Expertise



Nigel Lange Managing Director & CEO

30+ years experience in medical device industry

Served as Group COO and Interim Group CEO of Sirtex Medical



30+ years experience in diagnostic and interventional radiology

EMEA Medical Director of Sirtex Medical from 2005 - 2020



Turner Head of Medical Affairs

David

experience in pharmaceutical, medical device and health technology industries



Henk Tissing Director of Clinical Development

25+ years industry experience in oncology with pharmaceuticals and medical devices.

Clinical development roles at Sirtex Medical, BTG, A-Z & Sanofi Aventis

Olaf Michaelsen Director AREA<sup>1</sup>

25+ years experience in implantable medical devices

Previous commercial roles at Sirtex Medical, Medtronic and LifeCell Karl Pechmann CFO

Former CFO of Kyckr, and has held several finance roles for listed and multi-national organisations



Nicole Wilson VP, Regulatory Affairs and Quality

15+ years regulatory medical device experience

David James Global Head, Manufacturing & Operations

25+ years of pharmaceutical manufacturing operations experience

## Achievements so far



PanCO Study completed



CE Marking obtained



Breakthrough device designation achieved in US, EU, UK, Singapore



**Enabled HDE pathway for bile duct cancer in US enabled** – application submitted to FDA



**FDA:** Food and Drug Administration **HDE: Humanitarian Device Exemption** \* Distal cholangiocarcinoma (DCC or bile duct cancer)

## **Go-To Market Execution Progress**

Preparation of **OSPREY Sites** 

Ethics applications in progress in over 25 hospitals in the following markets: UK. Germany, France, Spain, Italy, Portugal, Turkey and Israel.

Training to be completed by end of November 2021

**Market Access** and reimbursement



application for Submission through **German Hospitals** 

Clinical development plan in progress

to address regulatory as well as

clinical outcome requirements from the scientific community

Clinical **Development Plan** 

**Utilise the SAS Special Access Scheme** 



**Treatment permissible** under SAS scheme in Australia as long as we do not promote the therapy

**HDE Application: Distal** cholangiocarcinoma

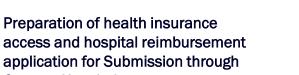


Humanitarian Device Exemption (HDE) application submitted with the US FDA for its OncoSil<sup>™</sup> device in the treatment of distal cholangiocarcinoma

Dataset updated to include final safety and efficacy data from the PanCO and OncoPaC-1 trials as per request from the FDA

The data set submitted October after delays due to COVID restrictions at sites. Awaiting response and queries from FDA

FDA: Food and Drug Administration **HDE:** Humanitarian Device Exemption



Exploration of health insurance market access avenues in target markets

Initiated first steps in developing a global value dossier and budget impact analysis for the requirements of health insurances and health technology assessment agencies

## HDE Application for Distal Cholangiocarcinoma

### Where are we now?



to COVID-19 restrictions at Study sites.

## Commercial Opportunity Expansion

Current Position:	Expansion opportunity:
<ul> <li>Approved in:</li> <li>Europe (CE Mark) - New Zealand</li> <li>Switzerland - United Kingdom</li> <li>Singapore - Israel</li> <li>Malaysia - Turkey</li> <li>Hong Kong</li> <li>Private payer markets and limited hospital public funding</li> <li>In combination with gemcitabine-based chemotherapy</li> </ul>	<ul> <li>Commercialise OncoSII<sup>™</sup> device in the USA under FDA HDE approval</li> <li>Expand Label to include FOLFIRINOX chemo</li> <li>Alternative device delivery methods</li> <li>Secure US FDA PMA approval in LAPC</li> <li>Possible indication expansion</li> <li>Generate clinical evidence to access public payer markets globally: Secure reimbursement</li> </ul>

FDA: Food and Drug Administration HCPCS: Healthcare Common Procedure Coding System HDE: Humanitarian Device Exemption LAPC: Locally Advanced Pancreatic Cancer PMA: Pre-Market Approval

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