

ASX/ Media Release 23 October 2017

# Progress Update: Positive Early Study Results Presented at EANM Congress

**Sydney, Australia, 23 October 2017:** OncoSil Medical Limited (ASX: OSL) (**OncoSil Medical** or the **Company**) a medical device company focused on localised treatments for patients with pancreatic and liver cancer, is pleased to provide an overview of early study results presented at the European Association of Nuclear Medicine (EANM) Congress.

## **Key highlights**

100% Disease Control Rate (DCR) at Week 8
Early and substantial tumour volume reductions – up to 73% volumetric reduction observed 4
weeks post implant, Median volumetric reduction 34.5% at 4 weeks post implant
No Serious Adverse Events attributed to the device or implantation procedure
Device delivery via Endoscopic Ultrasound (EUS) considered easy and uncomplicated

## Positive early study results presented to EANM in Vienna

Positive data from the first group of patients who completed computed tomography (CT) imaging in the 8, 16 and 24-week study follow-up periods was presented at the EANM Congress which took place in Vienna on 21 October 2017.

This early study data is consistent with previously completed studies that validated the safety, efficacy and delivery of the OncoSil<sup>TM</sup> device.

OncoSil Chief Executive Officer Daniel Kenny commented:

"We are pleased to announce the early results from our Global Pancreatic Cancer Clinical Trial, which represents an important milestone for Oncosil Medical. Not only do the results demonstrate excellent local disease control in subjects at Week 8, they also evidence the downstaging potential of the OncoSil ™ device. The early and substantial volumetric reductions seen in patients 4 weeks post implant were particularly pleasing to see. We are satisfied that the OncoSil™ device is clinically de-risked on the basis of these early emerging data."

# Positive feedback on OncoSil<sup>™</sup> received from medical professionals and physicians

Monash Medical Health Principal Investigator, Dr Marion Harris stated:

"We are encouraged by the positive early data from the first group of patients completing the Week 8 & 16 follow-up periods. The OncoSil™ device has a reassuring safety profile with no Serious Adverse Events attributed to the device or implantation procedure."



Dr Dan Croagh Pancreatic & Hepatobiliary Surgeon at Monash Medical Health commented:

"At Monash, we have been able to successfully implant OncoSil $^{\rm TM}$  on 8 occasions with no obvious complications related to the implantation procedure."

# Overview of key data presented to EANM

The European Association of Nuclear Medicine is the largest organisation dedicated to Nuclear Medicine in Europe. The EANM Annual Congress is the most valuable Nuclear Medicine meeting worldwide with over 6200 participants.

OncoSil's Chief Medical Office, Dr. Ashish Soman, presented early data from OncoSil's Global Pancreatic Clinical Study Programme.

A high-level overview of the results presented is set out below:

## **Clinical Performance**

- 14 subjects were implanted with the OncoSil™ device
- At the time of analysis:
  - 12 subjects had reached Week 8 radiological evaluation
  - 4 subjects had reached Week 16 radiological evaluation
  - o 1 subjects had reached Week 24 radiological evaluation
- Disease Control Rate (DCR) at Week 8 was 100%
- Notably, early and substantial tumour volumetric reduction observed in participants at 4 weeks after implantation; key statistics include:
  - Up to 73% volumetric reduction
  - Median volumetric reduction of 34.5%

#### Safety

To date, the study has confirmed a reassuring Safety profile for the OncoSil<sup>TM</sup> device, as confirmed by the First Independent Safety Review Committee:

- No "Serious Adverse Events" (SAEs) were attributed to device or implantation procedure
- SAEs only related to chemotherapy and/or complications arising from cancer progression
- No evidence of radiation toxicities
- No other safety concerns identified to date

#### **Implantation Procedure**

The OncoSil™ device delivery via Ultrasound guided endoscopy (EUS) is considered easy to use for implantation. The Company will continue to refine the implantation technique for maximum optimisation.

## **Global Pancreatic Cancer Clinical Study – next steps**

OncoSil continues to progress patient recruitment of its Global Pancreatic Cancer Clinical Study programme, with 28 subjects are now enrolled into the study group.



The Company will continue to recruit subjects beyond the initial 20 subject target to gather additional valuable clinical experience and to account for subject loss due to factors such as withdrawal on clinical grounds prior to implantation or protocol ineligibility.

#### **Notice of AGM**

The Company advises it will hold its Annual General Meeting (AGM) on Wednesday, 25 October 2017 at 11:00 AM (AEDT).

The AGM will take place at: The Offices of K & L Gates Level 31, 1 O'Connell St Sydney, NSW

- ENDS -

Company	Media
Mr Daniel Kenny	Ben Walsh
CEO & Managing Director	WE Buchan
E: daniel.kenny@oncosil.com.au	E: <u>bwalsh@buchanwe.com.au</u>
T: +61 2 9223 3344	M: 0411 520 012

#### **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 (Phosphorous-32), implanted directly into a patient's pancreatic tumours via an endoscopic ultrasound.

Treatment with OncoSil™ is intended to deliver more concentrated and localised beta radiation compared to external beam radiation. OncoSil Medical has conducted four clinical studies with encouraging results on tolerability, safety and efficacy. A CE Mark application to commercially sell OncoSil™ in the European Union (EU) is under review with commercial launch, subject to approval.

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. 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 \$1b.

Hepatocellular carcinoma (HCC) or liver cancer, is the 6th most common cancer in the world with 782,000 new cases diagnosed in 2012. While hepatocellular carcinoma can be treated by surgery or transplantation, the majority of patients with HCC have disease which is too advanced for surgery and their survival ranges from a few months to two or more years. The value of the hepatocellular cancer market is expected to triple in size to \$1.4b by 2019.