

ASX/ Media Release
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OncoSil announces positive Week 8 and 16 data for first 20 patients in global pancreatic clinical study

Sydney, Australia, 28 February 2018: 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 report positive Week 8 & 16 data for the first 20 patients enrolled in the Company's Global Pancreatic Cancer Clinical Study Programme.

Key highlights:

- **20 patients have reached the key Week 8, and 14 patients the Week 16 milestone**
- **3 of the first 20 patients implanted are now being actively considered by their clinical teams for surgical resection**
- **20 patient data shows excellent local disease control and safety at Week 8**
 - **Local Disease Control Rate (DCR) at Week 8 is 100%**
- **Encouraging Week 16 data for first 14 patients to reach the next milestone**
 - **Local Disease Control Rate (DCR) at Week 16 is 87%**
- **So far 4 of the first 20 patients implanted have achieved a partial response - PR**
 - (PR - Partial Response is defined by "RECIST 1.1" as a reduction in tumour longest diameter of at least 30% from baseline)
- **No Serious Adverse Events attributed to device or implantation procedure**
- **Device implantation via Endoscopic Ultrasound remains a method considered to be easy and uncomplicated**
- **Patient recruitment continues, with a total of 35 patients enrolled in the global study across Australia, UK and Belgium and 1 patient enrolled in the US.**
 - **27 patients successfully implanted with the OncoSil™ device.**
- **The Company anticipates providing 16-week data for the first 20 patients to the EU Notified Body, BSI by 31 May, 2018**

OncoSil Chief Executive Director Daniel Kenny commented:

"We are excited to share positive Week 8 & 16 data for the first 20 patients enrolled in our global Clinical programme. We are very pleased with the consistency of these results with the early data presented in Vienna in October 2017. As in previously completed studies the data show outstanding local disease control and tumour volumetric reduction when the OncoSil device is used with concomitant standard of care chemotherapy."

"The Company anticipates submitting 16 week data for the first 20 patients to the EU Notified Body, BSI by 31 May."

“We look forward to reporting further data as our enrolled subject’s progress through the study.”

Overview of Global Trial: updated key data

Pancreatic cancer is one of the most aggressive tumor types and one of the top 5 causes of cancer-associated death in the United States and the European Union. The overall prognosis for patients with pancreatic cancer remains poor with the 5-year survival rate for all stages of disease combined is only 5%. **Surgical resection is the only potential cure for pancreatic cancer**, however, less than 15% of patients are eligible for this resection procedure. The primary objectives in treating unresectable locally advanced pancreatic cancer patients, is to achieve tumour control, palliation of symptoms and prolongation of survival.

Oncosil’s global pancreatic clinical trial programme has a study population of unresectable (inoperable) locally advanced (non-metastatic) pancreatic cancer patients.

Key Clinical Performance

1. 27 patients have been implanted with the OncoSil™ device. At the time of analysis:
 - 20 patients had reached Week 8 radiological evaluation
 - 14 had reached Week 16 radiological evaluation
2. 100% Local Disease Control Rate (DCR) at Week 8 and 87% at Week 16
3. So far 4 of the first 20 patients implanted have achieved a partial response - PR
 - (PR - Partial Response is defined by “RECIST 1.1” as a reduction in tumour longest diameter of at least 30% from baseline)
4. 3 of the first 20 patients implanted are now being actively considered by their clinical teams for surgical resection. This is an encouraging development, raising the possibility of demonstrating improved outcomes in a patient group deemed inoperable at study entry. This important aspect will be closely followed as the study progresses and more information is obtained.
5. Substantial tumour volumetric reduction continued to be observed in participants at Week 8 & 16; key statistics include:
 - Up to 73% volumetric reduction at Week 8 (median volumetric reduction 29%)
 - Up to 72% volumetric reduction at Week 16 (median volumetric reduction 39.5%)

Safety

Three Independent Safety Review Committee meetings have confirmed the reassuring safety profile of the OncoSil™ device with:

- No “Serious Adverse Events” (SAEs) were attributed to device or implantation procedure
- Majority of SAEs related to chemotherapy and/or co morbidities
- No evidence of radiation toxicities
- No other safety concerns identified to date

Implantation Method

The implantation method of the OncoSil™ device, via Endoscopic Ultrasound (EUS), continues to be considered as straightforward.

Outlook

The Company will be presenting study data at two major upcoming international congresses:

- The 12th World Congress of the Federation of Nuclear Medicine and Biology in Melbourne in late April and
- the Digestive Disease Weekly (DDW) Conference in Washington in early June.

- ENDS -

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About OncoSil

OncoSil™ is a clinical-stage 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 four clinical trials 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 planned subject to approval.

The U.S Food and Drug Administration granted an Investigational Device Exemption (IDE) in July 2016 with approval to conduct a clinical study of the OncoSil™ device. The aim of the study will be to collect safety and effectiveness data required to support a Premarket Approval (PMA) application.

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.

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 materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. OncoSil 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.