ASX Announcement

1 April 2020

OncoSil Medical – Breakthrough device for the treatment of pancreatic cancer receives CE Marking approval

Key Highlights

- Oncosil Medical has received European CE Marking approval for its device for the treatment of locally advanced pancreatic cancer in combination with chemotherapy from the British Standards Institute (BSI)
- OncoSil™ device officially designated as a ***breakthrough device*** by BSI as per MEDDEV guidance
- COVID19 will impact launch preparedness, and delay the European commercial launch due to limited hospital access and global shipping disruption
- OncoSil will immediately commence multiple registration filings in key ASEAN and APAC markets which recognise CE Marking certification. This activity is unaffected by the COVID19 pandemic

Sydney, Australia – 1 April 2020: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**) is pleased to announce that the Company's OncoSil™ device has received CE Marking approval for the treatment of locally advanced pancreatic cancer (LAPC) in combination with chemotherapy, from the British Standards Institute (BSI). This first approval is a major milestone for OncoSil and allows for the OncoSil™ device to now be marketed and sold within the European Union and the United Kingdom.

Noting ongoing Brexit discussion the CE Mark granted to OncoSIl Medical provides market authorisation also to the UK as well as the EU.

The CE Marking certification is a validation of the OncoSil™ device and its clinical performance. Clinical studies by Oncosil have demonstrated a median overall survival of 16.1 months in patients treated with OncoSil™ plus chemotherapy (CT) almost double the accepted median overall survival in patients with unresectable pancreatic cancer[1].

OncoSil CEO and Managing Director Daniel Kenny said:

"Designation of the OncoSil™ device as a breakthrough device is a validation of our platform technology which can be used to treat multiple solid tumour types such as liver, biliary duct and of course pancreatic cancer."

"Having secured CE Marking approval, our focus is now on multiple registration filings in jurisdictions which recognise CE Marking certification. This activity is unaffected by the COVID19 pandemic," added Mr Kenny.

"The COVID-19 pandemic will impact our launch preparedness and delay our European launch as the Company expects disruptions due to limited hospital access in the coming months for new site initiation and training as well as shipping and logistical disruption.

We would like to thank our shareholders for their support through this long but ultimately rewarding journey."

OncoSil™ – a Breakthrough Device & platform technology

In addition to CE Marking approval the OncoSil™ device has now been officially classified as a **"breakthrough device"** as defined under EU Medical Device guidance. In the EU a "breakthrough device" is defined as one that delivers clinical benefit to patients for unmet medical needs which are life threatening, and for which current medical alternatives are insufficient or carry significant risks.

The OncoSil™ device is now officially designated as a breakthrough device in both the EU, and the UK as well as the US as per ASX announcement 18 March 2020.

OncoSil™ is a first in class medical device comprising microparticles containing phosphorus-32 (P-32), a pure beta-emitter radioisotope, implanted directly into a patient's pancreatic tumour via endoscopic ultrasound guidance.

Compelling clinical data from PanCO underpinned CE Marking approval

The CE Marking approval was achieved based on the compelling clinical outcomes from the PanCO study. Supporting the approval was a detailed comparative analysis (naïve in-direct treatment comparison) of the PanCO results with "state-of-the-art" treatment for unresectable locally advanced pancreatic cancer. The "state-of-the-art" treatments included a broad range of clinical studies of systemic chemotherapy (CT-only) and induction chemotherapy plus consolidated chemo-radiotherapy (ICT+CCRT) regimens supported in clinical guidelines for the treatment for unresectable LAPC.

This comparative analysis confirms that the OncoSil device, when combined with contemporary systemic chemotherapy regimens, demonstrates the following:

Excellent Local Disease Control (LDCR)

- **Local Disease Control Rates at 16 weeks ($LDCR_{16\ weeks}$) of 90.5% in the Per Protocol (PP) population (p=0.0001)** that received OncoSil™ plus CT, demonstrate that the PanCO study met its *a priori* primary performance endpoint **and convincingly demonstrates that OncoSil™ plus CT is better than CT alone.**

Prolonged Overall Survival (OS)

- **Prolonged median overall survival** of **16.1 months in the PP population**. (as of May 2019).
- **Almost double the accepted median OS for patients with unresectable pancreatic cancer[1]**
- **In the naïve indirect treatment comparison, the PanCO median OS results were significantly longer (*p*<0.001) than CT-only and ICT + CCRT regimens, representing a clinically relevant 20% reduction in the risk of death compared to CT-only and ICT + CCRT studies.**

Encouraging rate of Surgical Resection with Curative intent

- **An encouraging rate of surgical resection with curative intent** in nearly one-in-four PanCO patients (23.8%) were downstaged. This **rate is significantly greater than those reported in the CT-only and ICT + CCRT studies (*p*<0.001)** and, notably, the rate of R0 margin status was 80%.
- **In the systemic literature review analyses the CT-only resection rate was 7.7%, and the CT-only and ICT + CCRT resection rate was 9.9% compared with the PanCO resection rate of 23.4%**
- Surgical resection of pancreatic cancer, particularly in patients previously determined to be unresectable, profoundly **improves patients' prognosis from a five-year survival rate of 5% to greater than 20%.**

Prolonged Progression Free Survival (PFS)

- **Progression-free survival (PFS)** was also prolonged (9.3 months in the ITT and PP populations), and was **significantly greater than 'state-of-the-art' CT - only and ICT + CCRT studies (*p*<0.001).**

Higher Disease Control Rate

- **Disease control and overall response rates in the PanCO study – 100% and 31.0% respectively in the PP population** – underline the response following OncoSil™ administration and were again **significantly greater than the CT - only and ICT + CCRT studies in the naïve indirect treatment comparison.**

Marked Tumour Volume Reduction

- OncoSil™ treatment results in marked tumour volume reduction. Overall, treatment with OncoSil™ resulted in a **median maximal volumetric reduction of 52% from baseline.**
- **Median tumour volumetric reduction at 16 weeks was 38% (p<0.0001)**
- In the PanCO study a number of patients demonstrated **substantial tumour volume reductions up to 74% volumetric reduction at Week 8 and up to 90% volumetric reduction at Week 16**

Significant CA19-9 tumour marker reduction

- **There was a significant reduction in CA19-9 tumour marker with a median CA19-9 reduction of -77.8%; (p<0.0001)**

Superior outcomes to comparators

- The naive indirect treatment comparison confirms that the PanCO study results were consistently and statistically significantly better than the results from CT-only and ICT+CCRT studies, and clearly demonstrates that OncoSil™ plus CT provides clinically relevant benefits for patients with unresectable LAPC that are superior to those reported with CT alone

Safety

- **Excellent safety profile overall, with no evidence of significant safety concerns or unexpected/serious toxicities associated with the OncoSil™ device and/or implantation procedure over a prolonged study timeframe.**

- The OncoSil™ device provides a valuable treatment option in an area of high unmet medical need with an **acceptable safety and tolerability profile.**
- The clinically relevant benefits of OncoSil™ combined with systemic chemotherapy in appropriate patients with unresectable LAPC more than outweigh the identified risks and represent a **favourable risk-benefit profile.**

[1] **Loehrer PJ et al. J Clin Oncol 2011Nov 1;29 (31) 4105-12**

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Authorisation & Additional Information

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

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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.

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 intrahepatic and distal cholangiocarcinoma. 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 $1b.

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.