



ASX / Media Release
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Pancreatic Cancer Clinical Study Programme Update (OncoPaC)

Ethics Committee/IRB submissions lodged and under review

Sydney, Australia, 28 November 2016: 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 update on its global OncoPaC clinical study programme.

Highlights

- Johns Hopkins Hospital and MD Anderson Cancer Centre are the leading U.S. centres.
- Investigational Review Board (IRB) process has commenced and is on-going for these two U.S. centres.
- Guy's and St Thomas' Hospitals, London are the leading UK centres.
- Monash Health has agreed to be the lead Australian centre – ethics submission filed and under review.

University of Texas, MD Anderson Cancer Centre

MD Anderson Cancer Centre has agreed to participate and be a leading centre in the OncoPaC-1 study. The formal Investigational Review Board (IRB) process has commenced and is on-going.

The IRB approval is the final step for U.S. hospitals to agree to participate in a clinical study and recruit and treat patients under the agreed protocol for OncoPaC-1.

The Johns Hopkins Hospital, University Medical School

The Company is also pleased to announce the participation of The Johns Hopkins Hospital in Baltimore, Maryland as the other leading U.S. centre in the OncoPaC-1 study. The formal IRB process has also commenced at Johns Hopkins Hospital following lengthy collaborative work with OncoSil Medical.

Guy's and St Thomas' Hospitals

Guy's and St Thomas' are to be the lead centre in the United Kingdom for the global pancreatic clinical study programme. Guy's and St Thomas' have experience with the OncoSil™ device having previously participated in two earlier pancreatic cancer studies using the device in 2007/8 (DB2-201 & DB2-202).

Following confirmation of the lead UK centre, the Company has now commenced the central regulatory and governance applications in the UK.

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Monash Health

The Company is pleased to confirm that Monash Health has agreed to participate in the global pancreatic cancer clinical study programme. On November 11th the Company filed its Ethics Committee (HREC) submission and is currently under review. Once received HREC approval from Monash Health will facilitate Australian wide (except WA) ethics approval for other participating centres.

Monash Health is the largest public health service in Melbourne, Victoria providing services to more than one and a half million people. All cancer treatments are provided through the Monash Cancer Centre, one of Victoria's premier cancer facilities.

OncoSil Chief Executive Officer, Daniel Kenny commented:

"I am are delighted with the participation of these four prestigious centres in our global clinical programme.

These centres bring tremendous credibility as well as the benefit of being potential high volume recruitment sites. Our Team looks forward to working with these centres and their state of the art facilities.

I am pleased to report that we have another 11 centres in the U.S., UK and Australia currently evaluating the feasibility of participating in our study.

- ENDS -

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About OncoSil™

OncoSil Medical is a medical device company seeking to provide a new medical radiation treatment for cancer patients. OncoSil's lead product, OncoSil™ is silicon and phosphorous (³²P) beta emitter, able to be implanted by an endoscopically placed catheter in localised solid tumours of patients with pancreatic cancer. Treatment with the OncoSil™ device, known as brachytherapy, 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 for regulatory approval to commercially sell the OncoSil™ device in the EU and other non-US markets is under review with commercial launch planned for 2H2016, subject to approval. An Investigational Device Exemption 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.

About OncoPaC Clinical Study Programme

OncoPaC clinical study programme is a global, multi-centre, randomised, open label, pivotal efficacy and safety study of OncoSil™. The study is intended to include up to 30 centres in the United States and other international markets including the United Kingdom, Europe, and Australia. A total of 300 subjects will be recruited with locally advanced unresectable adenocarcinoma of the pancreas and eligible subjects will be randomised to either OncoSil™ plus standard chemotherapy treatment or standard chemotherapy treatment of gemcitabine or gemcitabine + nab-paclitaxel alone. In the investigational arm, OncoSil™ microparticles will be implanted intra-tumourally via endoscopic ultrasonography."

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.

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