



ASX / Media Release
2 August 2016

IDE Approval from the U.S. Food and Drug Administration OncoPac-1 U.S and International Clinical Study

Investor Call to discuss IDE along with Quarterly Results at 9.00am AEST, 3 August 2016

Sydney, Australia, 2 August 2016: OncoSil Medical Limited (ASX: OSL) (**OncoSil Medical** or the **Company**) a late stage medical devices company focused on localised treatments for subjects with pancreatic and liver cancer, is pleased to announce that it has received Investigational Device Exemption (**IDE**) approval from the U.S. Food and Drug Administration (**FDA**). The Company will now initiate a pivotal clinical investigation for OncoSil™ for the treatment of eligible subjects with pancreatic cancer.

OncoPac-1 U.S and International Clinical Study

As previously advised, the Company had filed an IDE Amendment with the FDA for its planned global clinical study of OncoSil™ for the treatment of pancreatic cancer (**OncoPac-1**). This followed an intensive eight month process of submissions and interactions with the FDA.

The Company has received notification from the FDA that the IDE Amendment submission has been approved thereby clearing the way for the Company to initiate its planned global clinical study, OncoPac-1.

The key details of OncoPac-1 study are as follows:

- OncoPac-1 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;
- In this pivotal study, a total of 300 subjects will be recruited with locally advanced unresectable adenocarcinoma of the pancreas. Stage 1 of the Study consists of 20 subjects across a maximum of 5 centres in the United States. These patient data will be subject to an FDA review focused on the safety profile;
- Following the successful completion of Stage 1, 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;
- Primary Efficacy Endpoint is Local Progression Free Survival (LPFS). Secondary Endpoints include Progression Free Survival (PFS), Overall Survival (OS), Pain Scores, Body Weight, Safety & Tolerability, and Performance Status. Quality of life measures will be studied;
- OncoPac-1 Study is expected to enrol the first subject in early 2017 and recruitment is anticipated to take approximately 2 years, with each patient to be followed until disease progression. Subjects are then followed for overall survival until death, or until the last enrolled study patient has completed 52 weeks of overall survival follow-up.

OncoSil Chief Executive Officer, Daniel Kenny commented:

“We are delighted to receive FDA approval for the IDE which is a significant milestone in our regulatory pathway and a validation of our product and supporting processes to commence this important clinical study. This achievement in only eight months from submission is a testament to the quality of the work that our dedicated and highly experienced team has undertaken and I would like to acknowledge and thank them.”

“We have also been active in a number of preparatory steps to support the initiation of the OncoPac-1 Study. We have been working to secure leading Principal Investigators, key hospitals and centres in the United States, Europe and Australia.”

“The IDE Approval is beneficial in supporting our ongoing CE mark application and we remain confident of obtaining our CE Mark in the near term. Our clinical team continues to advance the engagement with leading clinicians and centres in Europe, with the aim of treating both Study subjects and commercial cases, once we achieve our CE mark.”

Investor Conference Call

The Company will hold a conference call at **9.00 a.m. AEST on Wednesday, 3 August 2016** to discuss the Company’s financial results for the Quarter, the business outlook, and the IDE approval. The Company’s Chief Executive Officer and Managing Director Daniel Kenny will host the call.

To access the call please use the following details: Conference ID: 457277

Australian Toll Free:	1800 908 299
Australia Local (if dialing from international location):	+61 2 9007 8048
New Zealand Toll Free:	0800 452 795
Hong Kong Toll Free:	800 968 273
Singapore Toll Free:	800 616 2288
United Kingdom Toll Free:	0800 051 1453
United States/Canada Toll Free:	1855 624 0077

– ENDS –

Company	Investor Enquiries	Media
Mr Daniel Kenny CEO & Managing Director E: daniel.kenny@oncosil.com.au T: +61 2 9223 3344	David Allen or John Granger Hawkesbury Partners E: dallen@hawkesburypartners.com T: +61 2 9325 9046	James Moses Mandate Corporate E: james@mandatecorporate.com.au M: +61 420 991 574

About OncoSil

OncoSil is a clinical-stage medical device company seeking to provide a new medical radiation treatment for cancer subjects. OncoSil’s lead product, OncoSil™ is silicon and phosphorus (p32) beta emitter, able to be implanted by an endoscopically placed catheter in localised solid tumours of subjects 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 has conducted four clinical trials 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 to conduct a clinical trial of the OncoSil™ device aimed at supporting an FDA 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 subjects 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.

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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 subjects 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 as at the date of this presentation 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 national and international 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, nor that that any specific objective of the Company will be achieved or that any particular performance of the Company or of its shares will be achieved. In particular, the Company's expectations regarding the approval and commercialisation of the product candidates could be affected by, amongst other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; changes in legislation or regulatory requirements, 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 Company, products, product candidates, financial results and business prospects. Should one or more of these changes, 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. You are urged to consider all of the above and advice from your own advisers carefully in evaluating the forward-looking statements and are cautioned not to place undue reliance on the forward-looking statements. The information in this presentation is not financial product advice, is not an offer to invest in the securities of OncoSil and does not take into account your investment position or objectives, financial situation or any particular requirements.