



ASX / Media Release
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Regulatory Update

Progress on CE Mark and IDE submissions for OncoSil™

Sydney, Australia, 30 June 2016: OncoSil Medical Limited (ASX: OSL) (**OncoSil Medical** or the **Company**) a late stage medical device company focused on localised treatments for patients with pancreatic and liver cancer, is pleased to provide an update on its regulatory submissions.

European Union – CE Mark

The Company advises that in May 2016, it submitted further material in support of its CE Mark application for the OncoSil™ product in response to all requested questions received from the Notified Body, BSI, which is assessing the submission. Since then, no additional follow up questions have been received from BSI.

The Company remains confident of a successful outcome in its CE Mark which it believes could be in the near term, thus enabling to commencement of commercial sales of OncoSil™ in the European Union and application for commercialisation in Asia Pacific markets.

United States – Investigational Device Exemption

Today, the Company filed an Investigational Device Exemption (IDE) Amendment with the U.S Food and Drug Administration (the **FDA**) for its planned global clinical study of the OncoSil™ for the treatment of pancreatic cancer. This detailed submission followed ongoing and recent interactions with the FDA, the Company and its advisers.

As previously announced, the Company has progressed its IDE submission over the last six months, with the key events as follows:

- December 2015, IDE submission first filed following a six month pre IDE consultation process
- February 2016, additional data package of 1,700 pages filed in response to FDA questions
- March 2016, meeting with relevant Medical, Branch and Divisional Directors of the FDA
- April to June 2016, ongoing interactions between the Company's advisers and FDA
- 30 June 2016, IDE Amendment filed with the FDA

While there can be no guarantees, the Company remains confident of a successful outcome with the FDA which it believes could be in the near term. The IDE approval and the collection of the study data will be used to support a Premarket Approval (PMA) application and enable the Company to commercialise OncoSil™ in the United States, one of the world's largest healthcare markets.

Commenting on the progress, CEO, Mr Daniel Kenny said:

"We are delighted with the progress we have been making to prosecute and progress both our CE mark and IDE submissions. In particular, the filing today with the FDA is the culmination of an intense period of work by our team and advisers to prepare additional information in response to matters that have been raised in our Q-Submissions meeting and other interactions with the agency in recent months.

While we had initially hoped this IDE process would be completed in the first half of 2016, we believe a positive outcome is still achievable in the near term. Our progress is also consistent with the FDA's published data that for 2015 72% of IDE submissions were approved within two Q&A cycles. OncoSil is now concluding the first Q&A cycle.

We understand that many of our shareholders and investors are eagerly awaiting both the CE mark and IDE and appreciate their ongoing patience as we progress through these two regulatory processes."

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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 for 2H2016, subject to approval. An Investigational Device Exemption has also been lodged with the U.S Food and Drug Administration to seek approval to conduct a global 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.