



ASX ANNOUNCEMENT

Market Update

Sydney, Australia, 1st March 2016: OncoSil Medical Limited (ASX: OSL) (**OncoSil Medical** or the **Company**) provides the following update on its activities since the Quarterly Announcement on 28 January 2016.

Commercialisation

The Company continues to be in active engagement with the Notified Body for the CE Mark submission. By way of additional background on the activities being undertaken in relation to the CE Mark:

- During January and February 2016, the Company prepared detailed responses to outstanding questions received from the Notified Body. The Company has been advised that the issues raised in three memoranda from the Notified Body have now been closed out;
- the Company is currently finalising a response with material it expects to be completed for submission to the Notified Body within the next two to three weeks;
- The Notified Body plans to schedule a face to face meeting with the Company as a means of addressing the material and any questions, as soon as practicable.

The time that the Notified Body may take to complete its final review and provide a recommendation is expected to be in the near term. The Company acknowledges that the CE Mark filing is complex and that the process has been complicated and taken longer than anticipated, partly because the pancreatic and liver cancer indications sought are part of a single CE Mark submission.

Accordingly, a final decision on the Company's CE Mark may not be forthcoming before the end of Q1 2016. The Company remains confident in its submission for CE Mark being granted, thereby enabling commercial sales to commence in the European Union and application for TGA approval in Australia.

Clinical

The Company is also actively pursuing its Investigation Device Exemption (**IDE**) with the United States Food and Drug Administration (**FDA**). The Company filed for the IDE on 10 December 2015 and in February an additional data package of approximately 1700 pages was filed in response to FDA questions. The IDE submission process is proceeding and a face-to-face meeting with the FDA will be sought. With an IDE granted the Company would then proceed with a global clinical study aimed at securing US marketing approval.

Corporate

As recently announced, Regal Funds Management became a substantial shareholder in the Company, following the \$10m Placement completed on 10 February 2016. The Company is pleased to welcome a quality institutional investor to the share register and remains committed to broadening the institutional shareholder base.

The Company is pleased to advise that the Van Leeuwenhoeck Institute has released an updated Research Report which is available on the Company's website.

ENDS

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About OncoSil Medical Ltd

OncoSil Medical Ltd (OncoSil Medical) is a clinical-stage Australian Lifesciences company with the aim is to provide new technologies for safer medical radiation treatments. OncoSil Medical's lead product is OncoSil™ with the first target indication being pancreatic cancer. OncoSil™ is a silicon and P32 (phosphorus) pure beta emitter with the potential to be used medically as a brachytherapy treatment. The OncoSil™ device delivers more concentrated and localised beta radiation compared to external beam radiation. OncoSil Medical has previously conducted four clinical trials with encouraging results on tolerability, safety and efficacy. There is also potential use for OncoSil™ in other solid tumours outside of pancreatic cancer. FDA and CE Mark approval for pancreatic cancer is the core focus of OncoSil Medical.

Pancreatic Cancer

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 liver cancer

Hepatocellular carcinoma (HCC) is the 6th most common cancer in the world with 782,000 new cases diagnosed in 2012. It's very poor prognosis makes HCC the third leading cause of cancer related mortality responsible for approximately 600,000 deaths annually. Hepatocellular carcinoma can be cured by surgery or transplantation. The vast majority of patients with HCC have disease which is too advanced for surgical intervention and as a consequence survival ranges from a few months to two or more years depending on the liver function at diagnosis and the extent of tumour invasion. The value of the hepatocellular cancer (HCC) market is expected to triple in size to \$1.4b by 2019.