



**ASX / Media Release  
14th December 2015**

## **OncoSil™ US FDA Investigational Device Exemption (IDE) submitted**

### **Positive, ongoing progress with CE Mark application**

**SYDNEY, 14th December, 2015: OncoSil Medical Limited (ASX: OSL) (OncoSil Medical, the Company)** is pleased to announce that it has filed an Investigational Device Exemption (IDE) with the US Food and Drug Administration (FDA) for its lead product candidate, the OncoSil™ localised radiation treatment for cancer.

This is a significant milestone in the development pathway for OncoSil™ in pancreatic cancer and is the first step towards securing FDA commercial approval for OncoSil™ under a Pre-market Approval (PMA).

Subject to an IDE being granted, OncoSil Medical will commence a clinical study under the FDA to support the PMA. A PMA will allow the Company to commercially market OncoSil™ in the USA.

The Company formally filed its IDE submission on 10<sup>th</sup> December 2015 after successfully completing a lengthy pre-IDE process. The pre-IDE process involved an FDA review of the proposed Clinical Investigational plan including the endorsement of clinical endpoints and outcomes measures.

The IDE submission is the culmination of a detailed body of preparatory work conducted by OncoSil's medical and regulatory team over a six month period, which was undertaken in parallel with its Conformité Européenne (CE) Mark application process and ongoing review with the European regulatory body.

OncoSil Medical is pleased to report significant, positive progress with its CE Mark application, and the process remains ongoing. The formal review continues with the Notified Body and the Company anticipates a decision in the New Year.

OncoSil Medical CEO, Daniel Kenny said:

*"I am delighted to report that we have filed our Investigational Device Exemption submission with the US FDA. This represents a key milestone in the development timeline for OncoSil™ in the USA. In conjunction with our ongoing CE Mark process with the European regulator, the Company now has an active global regulatory licensing pathway"*

#### **US Pancreatic cancer market opportunity**

According to the most recent American Cancer Society statistics, the number of new cases of pancreatic cancer in the United States in 2015 is expected to be 48,960. Pancreatic cancer has a poor prognosis and is responsible for a relatively high percentage of cancer-related mortality.

The number of deaths in 2015 is expected to be 40,560. Pancreatic cancer is the 4<sup>th</sup> leading cause of cancer mortality in the US, after lung cancer (158,000), colon cancer (49,700) and breast cancer (40,730).

The relative five-year survival rate for all stages of pancreatic cancer combined is approximately 5%.

There currently exists a large un-met medical need for viable, new treatment options for pancreatic cancer which OncoSil Medical aims to meet with OncoSil™. The estimated world-wide market opportunity for OncoSil™ in pancreatic cancer exceeds \$1 billion.

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#### **About OncoSil Medical Ltd**

OncoSil Medical Ltd (OncoSil Medical) is a clinical-stage Australian Lifesciences company with the aim 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 the treatment of pancreatic cancer are the immediate 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 6<sup>th</sup> most common cancer in the world with 782,000 new cases diagnosed in 2012. Its poor prognosis makes HCC the third leading cause of cancer related mortality responsible for approximately 600,000 deaths annually. Hepatocellular carcinoma can sometimes be cured by surgery or transplantation. However 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 size of the hepatocellular cancer (HCC) market is expected to triple in size by 2019 to \$1.4b.

#### **References**

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