ASX / Media Release
9th September 2015

EU Fast Track Review for CE Mark confirmed for 6th October

SYDNEY, 9th September, 2015: OncoSil Medical Limited (ASX: OSL) (OncoSil Medical, the Company) is pleased to announce that the Notified Body (Regulator) has confirmed that the Company has been scheduled for a Conformité Européenne (CE) Mark Fast Track review for OncoSil™.

This review has now been scheduled following the submission of the CE Mark Design Dossier for pancreatic and primary liver cancer (HCC) to the Notified Body on July 17.

The Fast Track review will assess OncoSil Medical's design dossier and make a recommendation in respect of the CE Mark for OncoSil™.

The Fast Track review will take place in the UK commencing October 6th 2015 and will be conducted over four days. Upon completion of this review the Notified Body will make a determination to either recommend the granting of CE Mark certification for OncoSil™, or ask the Company to provide additional information in order to obtain CE Mark certification.

CE Mark is the mandatory regulatory designation required to commercially market and sell OncoSil™ in the EU. A CE Mark for OncoSil™ would also facilitate commercialisation and sales in other major markets, including Australia, Canada, and Singapore.

OncoSil Medical CEO, Daniel Kenny said:
"I am delighted with the progress of our CE Mark process for the commercialisation of OncoSil™. The filing is the culmination of an intensive eight months of work by the technical team. We now look forward to meeting with the regulator, and to securing CE Mark for OncoSil™ and being in a position to offer a new treatment option for the dreaded diseases of pancreatic cancer and liver cancer."

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Contact:
Mr Daniel Kenny
Chief Executive Officer and Managing Director
E: daniel.kenny@oncosil.com.au
T: +61 2 9223 3344

James Moses
Mandate Corporate
E: james@mandatecorporate.com.au
M: +61 420 991 574
T: +61 2 8211 0612

About OncoSil Medical Ltd

OncoSil Medical Ltd (OncoSil Medical) is a clinical-stage Australian Lifesciences company. 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.

References

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