



ASX / Media Release
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OncoSil™ CE Mark Update – Fast Track Face to Face Phase completed

SYDNEY, 12th October, 2015: OncoSil Medical Limited (ASX: OSL) (OncoSil Medical, the Company) is pleased to provide the following update on its Conformité Européenne (CE) Mark application for the Company's OncoSil™ localised radiation treatment for cancer.

As previously advised (ASX announcement, 9 September 2015), OncoSil Medical was granted a Fast Track review by the European regulator to assess its CE Mark application for OncoSil™ in pancreatic and primary liver cancer (HCC).

OncoSil Medical now advises that the Fast Track Face-to-Face review phase has been completed, and it now awaits the final outcome of the review as the Notified Body continues its assessment over the coming weeks. The Company was pleased with the review meeting and anticipates that the Notified Body will make a decision in respect of the CE Mark for OncoSil™ in November.

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

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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.

References

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