ASX / Media Release
18 May 2015

OncoSil™ European Commercialisation On-Track

Highlights:

- **Commercialisation of the OncoSil™ localised radiation treatment for cancer in the EU remains on schedule.**
- **Following the recent granted of ISO certification for OncoSil™, filing remains on schedule for Conformité Européenne (CE) Mark approval in Q3, 2015.**
- **Company's plans to file for CE Mark in Liver cancer in addition to pancreatic cancer strengthens its filing position and carries no additional risk.**
- **OncoSil™ has clinically demonstrated target tumour regression (tumour shrinkage) in both solid tumour indications of pancreatic and liver cancer.**
- **Commercialisation in the EU and would also facilitate sales in other major markets.**
- **Global market for Pancreatic Cancer is US$1Bn and HCC Liver Cancer is an additional US$1.4Bn**

SYDNEY, 18th May, 2015: OncoSil Medical Limited (ASX: OSL) (OncoSil Medical, the Company) is pleased to provide the following update on progress of its commercialisation program for its lead product candidate, the OncoSil™ localised radiation treatment for cancer, and reports that commercialisation in the European Union (EU) remains on schedule for approval in Q3, 2015.

OncoSil Medical recently announced it had been granted ISO 13485:2012 and ISO 13485:2003 certification in respect of OncoSil™ for the design, development and control of manufacture of radioactive implantable medical device in the area of oncology (ASX announcement, 27 April 2015). This is a pivotal and key requirement for Conformité Européenne (CE) Marking of Medical Devices in the EU.

After extensive and meticulous careful review; all of the regulatory documentation are in order with both the internal regulatory team and by a group of external independent regulatory medical affairs consultants. CE Mark is the mandatory designation required by regulators to sell OncoSil™ in the EU.

OncoSil Medical will file for CE Mark in both pancreatic and primary liver cancer – hepatocellular carcinoma (HCC). HCC Liver cancer was added to the CE Mark filing after regulatory advice as it serves to considerably strengthen the filing position, and carries no additional regulatory risk. It comes after clinical studies conducted confirmed OncoSil™'s ability to demonstrate tumour shrinkage in both solid tumour indications of pancreatic and liver cancer.

The Company remains on schedule with its filing process for CE Mark, scheduled for Q3 approval this year, and plans for commercialisation. The Company will update the market on a detailed business strategy and commercialisation plan once CE Mark approval is granted.

OncoSil™ is an implantable device that emits radiation directly into a specific targeted tumour. It is classed by regulators as a class III medical device, not a drug. Importantly for OncoSil™'s commercialisation pathway,

medical devices typically require less clinical trial work to achieve commercial approval, which can equate to less funding and a shorter timeframe to approval compared to drug development.

A CE Mark for OncoSil™ would also directly facilitate commercialisation and sales in many other major markets, including Australia, Canada and Singapore. A separate study for US approval will be run shortly with a US FDA IDE approval expected later this year.

Global yearly market for pancreatic cancer is US$1Bn and in HCC liver cancer is an additional US$1.4Bn

OncoSil Medical CEO, Daniel Kenny said "I am delighted with the efforts of the regulatory and medical affairs team in securing ISO Certification in April. This certification is a key requirement for CE mark Approval.
In my career I have been involved with numerous commercially successful 'blockbuster' products in Europe and I am very excited to now be in the forefront of potentially a new radiation treatment for the dreaded disease of pancreatic & Liver cancer."

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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 and liver 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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