ASX / Media Release
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OncoSil Medical to pursue additional indication: Primary Liver Cancer (Hepatocellular carcinoma)

Highlights

- **OncoSil Medical plans to file for CE Mark in both pancreatic and liver cancer indications in H2, 2015**
- **CE Mark would facilitate commercialisation for both indications in the EU, Australia, NZ and Canada**
- **Two previous Phase II Clinical Studies of Oncosil™ in hepatocellular carcinoma (HCC) showed excellent results to support the CE Mark filing**
- **Results could more than double the market potential of Oncosil™**
  - **Entering the primary liver cancer market represents a new market opportunity estimated to be worth $1.4billion by 2019**
  - **The estimated total market opportunity for Oncosil™ in pancreatic cancer exceeds $1 billion**
- **The combined Pancreatic and HCC clinical data set demonstrates that the OncoSil device technology platform is capable of use in two solid tumour types**

SYDNEY, 16th March, 2015: OncoSil Medical Limited (ASX: OSL) (OncoSil Medical, the Company) is pleased to announce that it will file for CE Mark in both pancreatic and liver cancer indications in the second half of this calendar year.

The decision to actively pursue the hepatocellular carcinoma (HCC) (primary liver cancer) indication comes as a result of a detailed clinical and regulatory review led by new OncoSil Chief Executive Officer Daniel Kenny, and will result in the Company delivering a broader development program, targeting two of the most insidious and difficult to treat cancers.

OncoSil has previously conducted two Pilot Clinical Studies on the use of the OncoSil™ localised radiation therapy treatment in hepatocellular carcinoma.

Evaluations of safety data from these studies has indicated that OncoSil™ is well tolerated in patients with unresectable hepatocellular carcinoma, and the efficacy data indicated that OncoSil™ had induced significant reductions in tumour volume in the targeted tumours in the liver. These data and the clinical experience in pancreatic cancer demonstrate that the OncoSil technology platform is capable of use in two solid tumour types (refer Table 1 below for HCC tumour response after treatment with OncoSil™).

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Response of HHC Target Tumour after Single Fixed Dose of OncoSil™

Patient Number	% Change in target Tumour Volume	Response+
001	-44%	Stable Disease
002	-80%	Partial Response
003	-16%	Stable Disease
004	-43%	Partial Response
005	-100%	Complete Response
006	-100%	Complete Response
007	-100%	Complete Response
008	-35%	Stable Disease

+WHO definitions of tumour response * Denotes investigator's classification. A change of -100% indicated total disappearance of target lesions

Table 1: Response of HCC target tumour after treatment with OncoSil™

OncoSil Medical is delighted to add the hepatocellular carcinoma program to its development program. It continues to advance the development program for its US pancreatic cancer indication, including the OncoSil™ Pivotal Clinical Trial. This development activity remains a prime focus for the Company.

OncoSil Medical CEO Mr Daniel Kenny said:
"Our recently completed strategic clinical and regulatory review highlighted the fact that OncoSil Medical has sufficient clinical data to support a CE Mark submission for liver cancer in addition to our original plans for pancreatic cancer. Both cancers provide a difficult treatment challenge for oncologists, and there is a large unmet medical need for new, viable treatment options in both indications. Our goal is to provide a commercially available treatment option for pancreatic and liver cancer patients globally and to explore use of our technology in other solid tumour indications in the future. "

The OncoSil™ opportunity

Pancreatic cancer and liver cancer are devastating diseases and the treatment of both remains a significant clinical challenge. OncoSil Medical believes that new implantable radiotherapies such as OncoSil™ may have the opportunity to treat the diseases and the debilitating pain associated with it.

Over 280,000 patients globally will be diagnosed with pancreatic cancer this year and treatment remains a major unmet medical need with a market potential estimated to exceed $1 billion. The median survival after diagnosis is only five months. Surgery is only feasible in 15% of patients, and chemotherapeutic treatments work in only one in six patients.

Hepatocellular Carcinoma is the sixth most common cancer in the world with 782,000 new cases diagnosed in 2012.

It's very poor prognosis makes it the third leading cause of cancer-related mortality, responsible for approximately 600,000 deaths annually. The value of the hepatocellular cancer (HCC) market is expected to triple in size to $1.4b by 2019, which more than doubles the market potential of Oncosil. Surgery offers patients the most consistent and significant survival advantage, yet less than 20% of HCC patients are suitable for surgery at time of diagnosis. Even in patients who have surgery, long term survival remains low because of recurrent carcinoma and progressive liver disease.

Approximately 30% of inoperable HCC patients may benefit from existing therapies that prolong life but outcomes and survival of the remaining inoperable patients is extremely poor. Radiation therapy may be used, but has systemic side effects in an already sick patient population. Localised radiation therapy, such as that supplied by OncoSil™, may offer a potential treatment option without systemic side effects.

CE Mark is the mandatory designation required by regulators to sell OncoSil™ in the European Union, and as such is a key component of OncoSil™'s development pathway. An IDE submission represents a significant formal step in the FDA's commercial approvals process for OncoSil™ under a Premarket Approval (PMA).

OncoSil™ is an implantable device that emits radiation directly into a specific targeted tumour, and delivers radiation therapy locally for up to three months. The device is inserted directly into the centre of the tumour using well established technology. Radiation therapy, such as that supplied by OncoSil™, is known to kill tumour cells.

OncoSil™ is classed by regulators as a class III medical device, not a drug. In drug development human studies are typically undertaken as phase I, phase II and phase III studies. In medical device development studies are undertaken as pilot and pivotal/registration studies. Thus medical devices typically require less clinical trial work for approval, less funding and have a faster time to approval when compared to drug development.

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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.

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