ASX / Media Release
15th July 2014

Ethics Approval Granted for OncoSil™ Clinical Pivotal Trial in Pancreatic Cancer

Highlights

- **OncoSil Medical has secured Ethics Approval for the Australian component of its Pivotal Clinical Trial for the OncoSil™ localised radiation treatment for pancreatic cancer - a major un-met medical need.**
- **OncoSil™ represents a potential advancement in the treatment of pancreatic cancer.**
- **Ethics Approval is a significant advancement in OncoSil™'s trial process and the Company will now seek to finalise arrangements for trial hospitals to commence patient recruitment.**
- **Company also continues to make preparations for an Investigational Device Exemption submission for OncoSil™ to the US Food and Drug Administration.**
- **OncoSil™ is an implantable device that emits radiation directly into a pancreatic tumour and delivers radiation therapy locally for up to three months.**

SYDNEY, 15th July, 2014: OncoSil Medical Limited (ASX: OSL) (OncoSil Medical, the Company) is pleased to announce that it has been granted Ethics Approval for the Australian hospital sites for the Pivotal Clinical Trial for its lead product candidate, the OncoSil™ localised radiation therapy treatment for pancreatic cancer.

The Ethics Approval for the Australian sites in the OncoSil™ Pivotal Clinical Trial is a significant advancement in the product's trial process, and is the culmination of a detailed ethics submission process with its Hospital Ethics Committee, over the past 4 months.

With Ethics Approval in place for the Australian component of the trial, OncoSil Medical will now work to finalise arrangements for the first group of hospitals to commence recruiting patients into the OncoSil™ Pivotal Clinical Trial. The Company anticipates that the first trial hospitals will be in Australia.

The Company also advises that it continues to make preparations for an Investigational Device Exemption (IDE) submission for OncoSil™ to the US Food and Drug Administration (FDA), and expects to submit an IDE in the near future. An IDE submission would represent a significant step in the regulatory pathway for OncoSil™, and is the the first step towards securing the FDA's commercial approval for OncoSil™ under a Premarket Approval (PMA).

OncoSil™ is an implantable device that emits radiation directly into a pancreatic tumour, and the surrounding pain conducting nerves, 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 in a short 15-30 minute procedure. Radiation therapy, such as that supplied by OncoSil™, is known to kill tumour cells.

ONCOSIL MEDICAL LIMITED ABN 89 113 824 141 ASX | OSL
Suite 807, Level 8, 1 Alfred Street Sydney NSW 2000 AUSTRALIA
TELEPHONE +61 2 9223 3344 FACSIMILE +61 2 9221 8535
WEB www.oncosil.com.au

OncoSil Medical announced in March (ASX announcement, 17 March 2014) that it had commenced its Pivotal Clinical Trial for OncoSil™. If positive, data generated by the trial may facilitate the commercialisation of OncoSil™, including focus on the US, which is the world's largest health care market.

The Company will provide further updates on the progress of the trial in due course.

OncoSil™ is classified 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.

OncoSil Medical CEO Dr. Neil Frazer said:
"We are delighted with the continued progress achieved in OncoSil™'s clinical development program. The grant of Ethics Approval for the Australian arm of the trial is another step in the product's development pathway, and the OncoSil team continues its work to advance the trial process. Over the coming months we look forward to bringing the first group of trial hospitals on-line and commencing the patient recruitment process."

The OncoSil™ Pivotal Clinical Trial

The Pivotal Clinical Trial for the OncoSil™, which also has the potential to be a Global Registration Study, is a major milestone in the Company's development pathway to commercialise OncoSil™ as a viable treatment option for pancreatic cancer patients in global markets.

The Pivotal Trial for OncoSil™ in pancreatic cancer will enrol 150 patients across 20 trial sites. It will compare patients receiving standard-of-care (for pancreatic cancer it is chemotherapy treatment) with patients receiving standard-of-care plus OncoSil™ treatment, in a randomized and controlled fashion. 150 patients will be randomized. 100 subjects will receive OncoSil™ plus chemotherapy and 50 patients will receive chemotherapy alone.

If positive, data generated by the trial may facilitate the commercialisation of OncoSil™, including in the US, which is the world's largest health care market.

Pancreatic cancer and the OncoSil™ opportunity

Pancreatic cancer is a devastating disease and treatment remains a challenge. OncoSil Medical believes that new implantable radiotherapies such as OncoSil™ may have the opportunity to treat the disease and the debilitating pain associated with it. In the US, over 40,000 patients are diagnosed with pancreatic cancer each year.

Treatment of pancreatic cancer remains a major unmet medical need, and the median survival after diagnosis is only five months. Surgery is only feasible in 20% of patients, and chemotherapeutic treatments work in only around 15% of patients.

Radiation therapy is 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.

ENDS

Contact:
Dr Neil Frazer
Chief Executive Officer and Managing Director
neil.frazer@oncosil.com.au

T +61 2 9223 3344
Twitter: @Dr_Neil_Frazer

About OncoSil Medical Ltd

OncoSil Medical Ltd (OncoSil Medical) is a clinical-stage Australian biotechnology 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 EMA 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 2010 280,000 people globally were diagnosed with pancreatic cancer including 43,140 Americans, 70,000 Europeans and 2,546 in Australia. 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 world-wide market for pancreatic drugs is projected by Global Industry Analysis to exceed US$1.2bn by 2015.