



ASX / Media Release
16th July 2014

GMP manufacturing process finalised for OncoSil™ in Pancreatic Cancer

- **Fully compliant GMP manufacturing processes have now been finalised to supply product for Pivotal Clinical Trial use**
- **The GMP manufacturing processes will support both CE mark related commercialisation and an IDE submission**
- **The manufacturing process validation involved requalification of facilities and equipment previously used to allow the company to move to the next stage**
- **The manufacturing supply chain has now been established to meet scalable future potential commercial demand**
- **A CE Mark is the mandatory designation required by regulators to permit sales of OncoSil™ in the European Union, and as such is a key component of the product's development pathway.**

SYDNEY, 16th July, 2014: OncoSil Medical Limited (ASX: OSL) (OncoSil Medical, the Company) is pleased to announce that the OncoSil™ manufacturing process has been revalidated for its localised radiation therapy treatment for pancreatic cancer to be used in its Pivotal Clinical Trial and in preparation for sales of the product under the CE mark process.

The Company advises that in conjunction with its German manufacturing partner, Eckert & Ziegler, it has completed a successful commissioning and re-validation of its manufacturing process and quality system to ensure that the Company is ready to supply OncoSil™ for the Pivotal Clinical Trial, and to meet future scalable sales of the product under the CE Mark.

OncoSil Medical also advises that it has sufficient supplies of the raw materials and intermediates required to manufacture the OncoSil™ product, for use in the Pivotal Clinical Trial globally. This supply of product raw materials is a key component of the product manufacturing logistics for the Pivotal Clinical Trial.

The manufacturing process review involved revalidation and requalification of facilities and work previously completed.

This process has confirmed that the manufacturing and quality systems are of a standard that will support manufacture of OncoSil™ for the trial and also for future commercial use.

The CE Mark audit process is in its final stages. This is being conducted by the British Standards Institute and once successfully complete will allow the Company to commence sales of OncoSil™ from its manufacturing site in Germany.

A CE Mark is the mandatory designation required by regulators to sell OncoSil™ in the European Union, and as such is a key component of the product's development pathway.

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 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 in 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 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.

OncoSil Medical CEO Dr. Neil Frazer said:

"We are extremely pleased to report that the manufacturing revalidation which will facilitate the production of OncoSil™ for use in its Pivotal Clinical Trial and also for future sales as part of the CE Mark process has now been completed. This represents a major component of the trial process, as it ensures we have sufficient, quality product to meet the demands of our trial participants at various locations across the globe. I would like thank all involved at the OncoSil Medical team for their efforts on this body of work, and also our German manufacturing partners at Eckert & Ziegler for their efforts and support."

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 up to 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.

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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.

About Eckert & Ziegler

With sales of €120 million and 620 employees, the Eckert & Ziegler Group (ISIN DE0005659700) is one of the world's largest providers of components based on isotope technology for medical, scientific and industrial use. The core businesses of the Group are cancer therapy, industrial radiometry and nuclear-medical imaging. Since 1999 Eckert & Ziegler has been listed at the Frankfurt Stock Market. The shares are traded in the Prime Standard segment.