New Technology To Provide Safer Radiotherapy Treatments

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OncoSil Medical to advance OncoSil™ Global Registration Plan

Highlights

- **Company aims to secure CE Mark and US FDA IDE approval in CY2H 2015.**
- **CE Mark would facilitate commercialisation in the EU, Australia, NZ and Canada.**
- **OncoSil has conducted a detailed strategic clinical and regulatory review of the OncoSil™ device program led by new CEO Daniel Kenny.**
- **Based on this review the previously communicated Pivotal Study will be redesigned.**
- **Redesign work ongoing in consultation with medical, scientific and regulatory experts.**
- **Active patient recruitment into Pivotal Study expected to commence CY3Q, 2015.**

SYDNEY , 25 February, 2015: OncoSil Medical Limited (ASX: OSL) (OncoSil Medical, the Company) is pleased to announce plans to advance Global Registration for its lead product candidate, the OncoSil™ localised radiation treatment for pancreatic cancer.

Under the leadership of new Chief Executive Officer Daniel Kenny, OncoSil has conducted a detailed strategic clinical and regulatory review of the OncoSil™ device program, and as a result has determined to aggressively pursue a global registration program in pancreatic cancer.

The Company aims to secure both CE Mark and FDA Investigational Device Exemption (IDE) approval for OncoSil™ in pancreatic cancer in CY2H 2015.

The CE Mark would facilitate the commercialisation of OncoSil™ in the European Union, Australia, NZ and Canada.

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

An IDE submission represents a significant formal step in the FDA's commercial approvals process for OncoSil™ under a Premarket Approval (PMA). A key component of the IDE submission is the conduct of the Pivotal Study. Based on the findings of the recently completed clinical and regulatory review the design of the currently proposed Pivotal Study will be comprehensively reworked.

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The Company will provide further updates on the new design of the Pivotal study before the end of CY2Q, 2015 following receipt of scientific advice from Regulatory Authorities. Active patient recruitment into the Pivotal Study is now expected to commence in CY3Q, 2015.

OncoSil Medical CEO Daniel Kenny said:

"Following our strategic review the Company is now better positioned to secure both the CE Mark and US FDA IDE this year. Our Pivotal study will now commence active recruitment in CY3Q following redesign based on comprehensive expert feedback including scientific advice from regulatory authorities"

OncoSil™ is an implantable device that emits radiation directly into a pancreatic 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.

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 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 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.

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