



ASX / Media Release
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First subject recruited for Global Pancreatic Clinical Study Programme

Highlights

- **First subject recruited for global clinical study in pancreatic cancer by Monash Health, Melbourne**
- **This subject is the first in a total of 20 subjects required to meet the Supplemental data request to secure CE Marking**
- **Company well positioned to provide supplemental data, with 16 leading centres confirming participation in the clinical programme**
- **St Vincent's Hospital, Sydney received Ethics approval on 16 March to participate in the global study**

Sydney, Australia, 28 March 2017: OncoSil Medical Limited (ASX: OSL) (**OncoSil Medical** or the **Company**) a medical device company focused on localised treatments for patients with pancreatic and liver cancer, is pleased to announce that Monash Health has recruited the first subject for its global clinical study program in pancreatic cancer.

The first subject has completed all baseline assessments and will now commenced one month of chemotherapy prior to implantation with the OncoSil™ device.

The recruitment of the first subject represents a significant milestone in the clinical study process to date and is the culmination of many months of work by Monash Health and the Company in preparing the centre for study commencement.

Monash Health is the largest public health service in Melbourne, and has agreed to be the lead Australian study centre. It provides health care services to more than 1.5 million people. All cancer treatments are provided through the Monash Cancer Centre, one of Victoria's premier cancer facilities.

This patient is the first in a total of 20 subjects required to meet the supplemental data request from BSI, the Company's Notified Body to secure CE Marking for the OncoSil™ device. The Company is very well positioned to provide the supplemental data from its clinical study programme. To date, OncoSil Medical has confirmed the participation of 16 centres for its global pancreatic clinical study programme.

One of these centres, St Vincent's Hospital, Sydney received Ethics approval on 16 March and is expected to commence recruiting subjects for the study programme in the coming weeks.

OncoSil Medical is working with large recruitment centres, and many of the sites included in the study are top-tier cancer centres, including MD Anderson and John Hopkins in the US.

OncoSil Chief Executive Officer, Daniel Kenny commented:

“We are pleased to report that the first subject for our global pancreatic clinical programme was recruited from our lead Australian site, Monash Health. The data from this subject and 19 others to be recruited from tier-one centres in the US, UK and other Australian centres will contribute to our supplemental data request for CE Marking. We look forward to updating the market with our recruitment progress over the coming weeks.”

Participating Study Centres

USA

The University of Texas, MD Anderson Cancer Centre in Texas, USA -*joint lead US study centre*

The Johns Hopkins University Hospital, University Medical School in Maryland, USA - *joint lead US study centre*

The Moffitt Cancer Centre, Tampa, USA

Northwestern Memorial Hospital, Chicago, USA

Cedars-Sinai Hospital, Los Angeles, USA

United Kingdom

Guy's and St Thomas' Hospital, UK - *lead UK study centre*

The University of Leicester, UK

Hammersmith Hospital, London, UK

Addenbrookes Hospital, Cambridge, UK

The Royal Liverpool Hospital, UK

Belgium

The Institute Jules Bordet, Brussel, Belgium - *lead Belgian study centre*

Australia

Monash Health, Melbourne, Australia - *lead Australian study centre*, and

St Vincent's Hospital, Sydney, Australia

Westmead Hospital, Sydney, Australia

Royal North Shore Hospital, Sydney, Australia

Royal Adelaide Hospital, Australia

- ENDS -

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About OncoSil

OncoSil Medical is a medical device company seeking to advance radiation for cancer patients. OncoSil Medical's lead product, OncoSil™ is a targeted radioactive isotope (Phosphorous-32), implanted directly into a patient's pancreatic tumours via an endoscopic ultrasound.

Treatment with OncoSil™ is intended to deliver more concentrated and localised beta radiation compared to external beam radiation. OncoSil Medical has conducted four clinical studies with encouraging results on tolerability, safety and efficacy. A CE Mark application to commercially sell OncoSil™ in the European Union (EU) is under review with commercial launch, subject to approval.

An Investigational Device Exemption (IDE) has been granted by the United States Food and Drug Administration (FDA) to conduct a clinical study of the OncoSil™ device aimed at supporting a PMA approval. 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 (HCC) or liver cancer, is the 6th most common cancer in the world with 782,000 new cases diagnosed in 2012. While hepatocellular carcinoma can be treated by surgery or transplantation, the majority of patients with HCC have disease which is too advanced for surgery and their survival ranges from a few months to two or more years. The value of the hepatocellular cancer market is expected to triple in size to \$1.4b by 2019.

Forward Looking Statements

This document contains certain forward-looking statements, relating to OncoSil's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA and other authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialisation of the product candidates could be affected by, among other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. OncoSil Medical is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.