ASX Announcement

21 October 2024

OncoSil Medical Limited Receives UKCA Renewal Certificates Without Post-Market Restrictions

Sydney, Australia – 21 October 2024: Pancreatic cancer treatment device company **OncoSil Medical Limited (ASX:OSL)** ("**OncoSil**" or "**the Company**") is pleased to announce that it has successfully received UK Conformity Assessed (UKCA) renewal certificates from the British Standards Institution (BSI) for the OncoSil™ device, with no post-market restrictions. This certification highlights the solid clinical evidence supporting the safety of the OncoSil™ device and enables continued access to the UK market without additional compliance burdens.

The removal of all post-market restrictions will allow OncoSil to operate more efficiently in the UK, streamlining regulatory requirements, reducing associated costs and acceleratingthe sales cycle. The UKCA certification, issued by BSI, is an important regulatory milestone that reaffirms the company's commitment to maintaining high standards of safety and effectiveness in pancreatic cancer treatment.

In parallel, OncoSil is expecting to receive Medical Device Regulation (MDR) approval from BSI in the near future, which will further strengthen its market position across Europe and expand patient access to this innovative treatment.

Nigel Lange, CEO & Managing Director of OncoSil Medical, commented:

"Receiving the UKCA renewal certificates without any post-market restrictions from BSI is a major accomplishment for OncoSil Medical. This achievement not only reinforces the trust in the safety of our device but also simplifies our operations in the UK. We are also anticipating MDR approval from BSI shortly, which will unlock even greater opportunities across the European market."

Authorisation & Additional Information

This announcement was authorised by the Chairman of OncoSil Medical Limited.

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About OncoSil Medical

OncoSil Medical Limited (ASX:OSL) has developed a cancer treatment device, the OncoSil™ brachytherapy device, which is a critical component of a revolutionary brachytherapy treatment for locally advanced unresectable pancreatic cancer. This type of cancer is the 12th most common cancer in men and the 11th most common cancer in women across the globe, with some 500,000 new cases of pancreatic cancer detected every year. With pancreatic cancer typically diagnosed at a later stage, it has a poor prognosis for long-term survival[1].

The OncoSil™ device delivers a targeted intratumoural placement of Phosphorous-32 (^{32}P) in the treatment of locally advanced unresectable pancreatic cancer. This occurs via injection directly into a patient's pancreatic tumours under endoscopic ultrasound guidance and takes place in combination with gemcitabine-based chemotherapy.

The OncoSil™ device that has already received breakthrough device designation in the European Union, United Kingdom and United States for the treatment of locally advanced unresectable pancreatic cancer in combination with chemotherapy. CE Marking has additionally been granted for the OncoSil™ device, which can be marketed in the European Union, United Kingdom.

While clinical trials involving the OncoSil™ device continue to occur, the Company is simultaneously moving to commercialise this unique medical technology. It is currently approved for sale in 30+ countries including European Union, United Kingdom, Türkiye and Israel, with initial commercial pancreatic cancer treatments using the device already undertaken in Spain, Italy and Israel.

To learn more, please visit: www.oncosil.com/

References: 1. https://www.wcrf.org/cancer-trends/pancreatic-cancer-statistics/