OptiScan Imaging Limited
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ASX Announcement

15 October, 2018

Commencement of Clinical Trial
Assessment of Breast Cancer Margin with Confocal Laser Endomicroscopy (CLE)

Optiscan Imaging Limited ("Optiscan" or "the Company") is pleased to announce Ethics approval and commencement of patient recruitment for the first stage in an intended four stage clinical trial using Optiscan's patented technology to assess the surgical margin in patients with carcinoma of the breast undergoing breast conservation surgery ("lumpectomy"). The clinical trial is being undertaken at Hollywood Private Hospital, in Perth with the Principal Investigators of Dr Philip Currie, Dr Peter Willsher and Dr Jespal Gill.

The ultimate goal of the four stages of the clinical trial is to assist both breast surgeons and pathologists to provide real-time determination of the required surgical margin reducing the risk of residual tumour, the need for repeat surgery and the associated emotional distress suffered by the patients. If achieved, these goals will have significant positive impact for patient welfare as well as substantially reducing the number of repeat operations and reducing associated costs for the patients, hospitals, insurers and the taxpayer.

The initial stage of the clinical trial focuses on examining ex-vivo excised breast tissue specimens by both CLE and standard histopathology in order to trial multiple imaging techniques to determine patterns of normal, non-malignant and malignant tissue without impacting the ability to undertake standard histopathology of the same specimens.

Breast cancer is the second most frequently diagnosed new cancer and has the second highest mortality rate of cancers in females. In 2017, there were 252,710 new cases of invasive breast cancer diagnosed in the United States and 17,730 new cases (28% of new cancers in females) diagnosed in Australia. Lumpectomies now account for approximately 60% of surgeries for early stage breast cancer.

The goal of a lumpectomy is to completely excise the tumour with a rim of healthy breast tissue called a "negative margin" with acceptable cosmesis, balancing the volume of tissue removed to obtain the negative surgical margins to improve survival, quality of life and body image. Currently, the determination of sufficient tumour margin is comprehensive histopathological analysis performed a few days after surgery. If successful, the use of CLE would enable this analysis to be performed in the operating theatre at the time of the initial operation with the histopathological analysis then later confirming complete primary excision with a negative margin.

Dr Peter Willsher, Breast Surgeon with the Breast Cancer Research Centre –WA, has been eager to embark on this study. He stated "Unfortunately, there is an important clinical problem with lumpectomies, with residual cancer at the surgical margin (positive margin) found in 20 to 30% of cases with these cases requiring early reoperation after the histopathological analysis has been undertaken. There are also

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multiple important negative consequences of a “positive margin”, which include the emotional trauma to patient, post-operative infections, poor cosmesis, prolonged hospital stay, delayed adjuvant therapy and higher costs. I hope that CLE will dramatically reduce this problem and consequences”.

Dr Jespal Gill, Consultant Anatomical Pathologist of Western Diagnostic Pathology, has commenced comparing the CLE imaging obtained using the Optiscan Five2 ViewnVivo system with the traditional histopathology imaging of the identical pathological tissue specimens. She stated, comparing the side by side imaging using the two techniques, “I am very impressed with the real-time high quality high resolution imaging at cellular level that this technology provides. The application of CLE in this clinical problem has a major opportunity to significantly reduce the need for reoperation in these vulnerable patients, something we all wish to avoid if we can”.

Optiscan and the Principal Investigators will collaborate on any product development, Ethics and regulatory approvals required for the next stages of the clinical trial.

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About Optiscan

Optiscan is an Australian company that has developed and patented miniaturised confocal microscopes, and is a global leader in the development and application of microscopic imaging and related technologies for medical and research markets.

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