ASX Announcement
1 June 2021

Update on seeking United States FDA approval and market entry

Optiscan Imaging Limited (ASX: OIL) ('the Company' or 'Optiscan') is pleased to provide an update on progress relating to its preparation for lodgment of its application for United States Food and Drug Administration (FDA) 510(k) clearance ("510(k) Application") to market its InVivage® device for Oral Cancer Screening and/or Surgery in the United States.

InVivage® is a next generation, non-invasive, instantaneous form of oral cancer screening targeting the severe health consequences of late stage diagnosis of oral cancer.

The Company has completed multiple internal and external validation requirements for the 510(k) Application at its premises and contract testing facilities in the United States ("Requirements"). During the course of meeting these Requirements, the Company has made further software and hardware improvements and undertaken additional testing and improvements in the functionality, useability and robustness of the InVivage® device.

The Company has continued to work closely with the Melbourne Dental School ("MDS") in relation to the dosing study ("Dosing Study") and the elements of the clinical study being carried out at MDS which will form part of the 510(k) Application ("Clinical Study"). The Dosing Study has been completed and the Clinical Study is expected to complete in the final quarter of 2021. Preparation of the 510(k) Application has commenced and will be completed once the Requirements and Clinical Study are finalized.

Optiscan is engaged in a detailed commercial planning process for entry into the US market including discussions with local and US based marketing agencies and the identification of potential US based team members and distribution partners.

For investor queries, please contact:
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This announcement has been authorised for release by the Board of OIL.

About Optiscan
Optiscan is a global leader in the development of microscopic imaging and related technologies for screening, surgery and medical research. Based in Melbourne, Australia, Optiscan has developed and patented endomicroscopic technology which enables real-time, 3D, 'in vivo' imaging of human tissue at the cellular level,with applications for cancer screening and surgical margin determination. Optiscan's technology has the capability to improve patient welfare, reduce hospital costs, improve accuracy and reduce the need for multiple procedures. The technology is approved for use in brain surgery and is involved in a number of oral and breast cancer studies.