ASX Announcement
15 May 2023

OPTISCAN ORAL STUDY PUBLISHED IN PRESTIGIOUS MEDICAL JOURNAL

Optiscan Imaging Limited (ASX: OIL) is pleased to announce the publication of readout results of its oral cancer imaging study conducted by Dr. Camile Farah and his team at the Australian Centre for Oral Oncology Research & Education. The study has been published in the prestigious, highly ranked international *Journal of Oral Pathology and Medicine* and highlights Optiscan technology is extremely accurate for diagnosing oral cancer and precancer. The data was presented at the American Academy of Oral Medicine annual conference in Savannah USA which drew significant interest and positive feedback from attendees.

The study, commenced by Dr. Farah prior to him joining the Company as CEO and Managing Director, assessed a cohort of 47 patients presenting with 63 distinct oral mucosal lesions. These participants were subjected to an optical biopsy using Optiscan's real-time in vivo confocal laser endomicroscope (CLE). The CLE images were captured live during clinical examination and assessed on-the-fly to provide an instantaneous diagnosis based on the presence of cellular and architectural features indicative of oral epithelial dysplasia and carcinoma using World Health Organisation (WHO) criteria.

The study revealed an extremely high diagnostic accuracy of 88.9% for the presence of dysplasia/carcinoma, with sensitivity of 86.8%, specificity of 92%, positive predictive value of 94.3%, and negative predictive value of 82.1%. Notably, 100% of cancer cases were accurately diagnosed using CLE in a clinical setting.

Dr. Farah said, "The study demonstrates that Optiscan technology is effective and highly accurate in visualisation and identification of dysplasia/carcinoma of the oral mucosa. The decision to adopt a consensus procedure involving 3 blinded anatomical pathologists, establishes strong correlation and concordance between Optiscan's CLE technology and traditional histopathology, affirming the excellent outcomes achieved through the clinical application of CLE. Importantly, utilisation of internationally accepted WHO diagnostic criteria of dysplasia for use with Optiscan's CLE technology will undoubtedly lead to earlier adoption of its InVivage® device once cleared."

Optiscan's Chairman, Mr Robert Cooke said, "The international publication of this study represents an important clinical milestone in demonstrating the viability of Optiscan's technology. The near-perfect agreement with traditional consensus histopathology, achieved without the need for physical tissue biopsy in a diagnostic oral imaging setting, provides a multitude of benefits to the Company. In the near term, it will support the acceleration of our De Novo submission for InVivage®. In the medium term, it will bolster our collaboration with Prolucid Technologies in the field of Artificial Intelligence and facilitate integration into our telepathology platform."

P: (61 3) 9538 3333
A: 16 Miles St, Mulgrave VIC 3170, Australia
W: www.optiscan.com

Dr. Farah elaborated further, “Not only does this publication show that the Optiscan technology is a viable and highly accurate point-of-care diagnostic approach to rapidly detect oral cancer and precancer in real-time, but looking ahead we envision coupling this with tissue biomarkers to drive advancements in molecular imaging for various clinical applications. We are excited about the future commercialisation of the Optiscan platform particularly as we cement our presence in the US and establish a new standard of precision surgery and digital pathology."

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This announcement has been authorised for release by the Board of Optiscan.

For investor queries, please contact:

Dr. Camile Farah
Chief Executive Officer & Managing Director
Optiscan Imaging Ltd
E: cfarah@optiscan.com

About Optiscan

Optiscan Imaging Ltd (ASX:OIL) is a global leader in the development, manufacturing, and commercialisation of confocal endomicroscopic imaging technologies for medical, translational and pre-clinical applications. Our technology enables real-time, non-destructive, 3D, *in-vivo* imaging at the single-cellular level.

We are driven by developing technology and its use to give healthcare providers and researchers the highest quality real-time microscopic imaging tools to enable the early detection and management of disease, improve patient outcomes, and reduce the high cost of curative medicine and associated procedures.

Our patent-protected proprietary technology, using specially miniaturised componentry, has created a pen-sized digital microscope, which can be used on any tissue it contacts to produce high resolution digital pathology images for cancer diagnosis and surgical margin detection in real-time. The aim of our technology development is for earlier diagnosis and subsequent treatment of cancerous tumours with expected associated improved patient outcomes.

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