FDA grants Australian breast cancer innovation 'Breakthrough Device Designation' status

PERTH, Western Australia, 3 May 2021: OncoRes Medical has received 'Breakthrough Device Designation' from the U.S. Food and Drug Administration (FDA) to expedite development of its Quantitative Micro-Elastography (QME) Imaging System. This innovative technology is designed to facilitate real-time tumour assessment to help surgeons more accurately identify and remove cancerous tissue—an approach that could **substantially improve outcomes in breast-conserving surgery (BCS) and reduce repeat operations for women with breast cancer.**

The FDA's Breakthrough Device program supports the timely development of technologies that have the potential to provide more effective treatment of life-threatening or irreversibly debilitating diseases or conditions. Under this program, OncoRes will benefit from an expedited regulatory review process. The designation also has the potential to provide automatic reimbursement coverage for the QME Imaging System upon FDA approval.

OncoRes Medical CEO, Dr Katharine Giles, said the OncoRes imaging system uniquely intensifies the surgeon's sense of touch, enabling real-time, high-resolution intraoperative assessment of the tumour cavity.

"We know that facilitating detailed assessments in-cavity may improve surgical accuracy and support complete tumour removal, the first time. Breakthrough Device Designation from the FDA is a strong endorsement of our technology and its potential to change, even save, lives. It provides a more efficient regulatory and reimbursement pathway in the U.S., ensuring earliest possible surgeon and patient access to the clinical and economic benefits of this world-class innovation," said Dr Giles.

OncoRes Medical CMO, Prof Christobel Saunders AO, said OncoRes Medical's QME Imaging System is a vital new tool for breast cancer surgeons performing BCS.

"The real-time, microscale detection of cancerous tissue in the surgical cavity provided by the QME Imaging System will be game-changing for breast cancer surgeons performing BCS. The improved surgical accuracy facilitated by the System will get us closer to a world where patients and their families will no longer have to endure the physical, psychological and financial burdens of repeat operations," said Prof Saunders.

Among women, breast cancer remains the most common cancer, the second most common cause of death from cancer and a leading cause of premature death. In the U.S. alone, over 325,000 women will be diagnosed with breast cancer this year. **Most of those women will elect to undergo BCS in preference to mastectomy to surgically excise the tumour and preserve the appearance and function of their breast. However, due to the limitations of technologies available to oncology surgeons today, the cancer will not be completely removed in many of those patients.**

"Approximately one in five women in the U.S. who undergo breast conserving surgery are required to return to theatre for a repeat operation to remove residual tumour. These repeat operations carry a higher risk of complications and create significant physical, psychological and financial burdens for patients, their families and the healthcare system – this is something we are working hard to change," said Dr Giles.

Cancerous tissue is well known to vary in stiffness from healthy tissue. Following the excision of the main specimen during BCS, the handheld QME probe is applied to a region of interest within the breast cavity and a micro-scale three-dimensional map of the elastic (stiffness) properties of the scanned region is generated. **These micro-scale maps of tissue stiffness offer surgeons an optical imaging method for assessing breast tissue for the presence of microscopic or otherwise non-palpable cancerous tissue remaining inside the breast cavity.** By facilitating the identification of residual cancerous tissue within the cavity, the OncoRes Medical QME Imaging System enables the surgeon to perform more complete removal of cancerous tissue during the surgery.

“We believe that all breast cancer patients deserve the opportunity to move beyond their breast cancer surgery knowing that all the cancer has been completely removed. In everything we do, we are moving confidently towards a world free from repeat operations,” said Dr Katharine Giles.

About OncoRes Medical

OncoRes Medical is a medical device company headquartered in Perth, Western Australia. The team is dedicated to eliminating the physical, psychological and economic burdens associated with repeat operations following breast-conserving surgery (BCS). OncoRes Medical is developing a hand-held, real time, intraoperative imaging device to improve the detection of residual tumour in the surgical cavity and provide surgeons with the confidence that no residual cancer remains in the breast. This innovation is based on technology from the University of Western Australia, Harry Perkins Institute and Western Australian Department of Health. The Company has been the recipient of Australian federal government grants, including a CRC-P grant which has contributed significantly to expediting the Breakthrough Device Designation process. **Learn more: oncoresmedical.com.**

Please note: The OncoRes Medical QME Imaging System is in research and development, and is not yet available for sale anywhere in the world.

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