OVARIAN CANCER TEST DELIVERS OUTSTANDING DIAGNOSTIC PERFORMANCE

INOVIQ Limited (ASX:IIQ or **INOVIQ**) is pleased to announce that its blood test for ovarian cancer screening has successfully completed an independent patient validation of its biomarkers and diagnostic performance, delivering outstanding test results with accuracy of over 94%. The EXO-OC blood test was performed using a more sensitive and specific method than used in routine pathology testing laboratories.

These results represent a major advancement in OC testing. In this study, exosomes were isolated from more than 500 blood samples, using INOVIQ's EXO-NET® on a fully-automated high-throughput robotic platform. Exosome ovarian cancer biomarkers, previously identified in the OC97 study, were measured using targeted mass spectrometry performed by The University of Queensland's (UQ) Centre for Extracellular Vesicle Nanomedicine. All targeted biomarkers were identified in ovarian cancer samples and their diagnostic performance was confirmed using ROC curve analysis and multivariate modelling. EXO-NET isolation of exosomes also identified additional cancer biomarkers for use in the future.

INOVIQ will now move to optimize the blood test on a commercial instrument platform and perform additional clinical validation as a precursor to delivering the test in a clinical laboratory.

The Director of the UQ Centre for Extracellular Vesicle Nanomedicine, Professor Carlos Salomon Gallo, said: *"This study demonstrated that the EXO-OC test identified ovarian cancer across all stages with an overall accuracy of over 94%. Notably, the EXO-OC test is particularly accurate in identifying early stages of ovarian cancer, achieving a sensitivity of more than 90% and specificity of 96% for stage I, where women have a 5-year survival rate of over 90%. Importantly, these results confirm that the ovarian cancer biomarkers were validated in an independent sample set, highlighting the robustness and reproducibility of INOVIQ's EXO-NET exosome isolation technology and UQ's proprietary biomarkers."*

CEO Dr Leearne Hinch said: "This biomarker panel showed exceptional performance in detecting early-stage ovarian cancer, where accurate diagnosis is most critical for improving patient outcomes. Early detection enables timely intervention, which is crucial for increasing survival rates and reducing disease progression."

Chairman David Williams said: *"This study provides clinical evidence to pursue a commercial product for early ovarian cancer detection."*

Authorised for release by the Company Secretary, Mark Edwards.

FURTHER INFORMATION

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ABOUT INOVIQ LTD

INOVIQ Ltd (ASX:IIQ) is a biotechnology company developing next-generation diagnostics and therapeutics for cancer. INOVIQ has commercialised its fast, efficient and scalable EXO-NET exosome isolation technology for biomarker discovery and diagnostics development, and the hTERT test as an adjunct test for bladder cancer. The company is advancing clinical-stage diagnostics for detection and monitoring of ovarian and breast cancers, and early-stage exosome therapeutics for solid tumours. For more information on INOVIQ, visit www.inoviq.com.

ABOUT UNIQUEST AND THE UNIVERSITY OF QUEENSLAND'S (UQ) CENTRE FOR EXTRACELLULAR VESICLE NANOMEDICINE

The UQ Centre for Extracellular Vesicle (EV) Nanomedicine bring together a multidisciplinary team of researchers and educators across the UQ and beyond to enable best research practices in EVs with the potential to translate research discoveries to rapid benefits from research breakthroughs.

Led by Professor Carlos Salomon Gallo, The Translational Extracellular Vesicles in Obstetrics and Gynae-Oncology Group, focuses on cutting-edge research into extracellular vesicles (EVs). For the past decade, the lab has been studying the role of EVs in ovarian cancer, along with their specific contents (e.g., miRNAs and proteins), which represent a valuable biomedical tool with potential applications as biomarkers for diagnosing and prognosing a wide range of diseases, including malignant tumours. One of the unique aspects of the group is its compliance with **ISO17025 standards** for EV isolation, analysis, and content characterisation, certified by **the National Association of Testing Authorities (NATA)**. This accreditation is critical for translating bench discoveries into clinical applications, as it ensures that the research adheres to the highest quality management standards. The Quality Management System (QMS) and NATA accreditation provide confidence in the reproducibility, reliability, and validity of the data, which is essential for meeting regulatory requirements. This level of rigor not only supports the group's ability to conduct world-class research and also facilitates the transition of EV-based discoveries from the laboratory to clinical practice, ensuring they meet the necessary standards for diagnostic and therapeutic use. For more information, visit https://clinical-research.centre.uq.edu.au/research/uq-centre-extracellular-vesicle-nanomedicine.

UniQuest is the commercialisation company of The University of Queensland (UQ). In partnership with UQ researchers, we create impact through the commercialisation of UQ intellectual property. Established in 1984, UniQuest's commercialisation track record positions UQ as the leader of research commercialisation in Australasia.

OVARIAN CANCER BACKGROUND

Ovarian Cancer (OC) is the world's deadliest gynaecological cancer and the eighth most common cancer in women worldwide. Globally, there were over 314,000 new cases, 207,000 deaths and 823,000 5-year survivors in 2020. The 2020 statistics in the USA were 24,000 new cases and 14,000 deaths, and Australia reported 1397 new cases and 1046 deaths.[1] The life-time risk of ovarian cancer for an average-risk woman is estimated at 1.2% and this increases to 35-70% in high-risk women with BRCA1 mutations.[2]

Ovarian cancer is often called the 'silent killer' as it is usually asymptomatic in the early stages of disease. It is often diagnosed at a late-stage after symptoms have appeared resulting in a poor 5-year survival rate of only 49%. Earlier detection by finding ovarian cancer when local rather than distant may increase 5-year survival from 30% to 93%.[3] Diagnosis is usually made using a combination of transvaginal ultrasound and a CA125 blood test that is often followed by advanced imaging and confirmed by tissue biopsy. However, there are no recommended screening tests for ovarian cancer in average-risk, asymptomatic women due to inadequate sensitivity and specificity of current tests for detecting early-stage disease.[4] *There remains a significant unmet clinical need for a non-invasive, accurate and reliable diagnostic test for the earlier detection of ovarian cancer*. Earlier detection may improve treatment options, health outcomes and survival rates for women diagnosed with ovarian cancer. The global ovarian cancer diagnostics market was US$1.7 billion in 2023 and is expected to reach US$2.9 billion by 2032.[5]

ABOUT THE EXOSOME-BASED OVARIAN CANCER (EXO-OC) TEST

The Exosome-based Ovarian Cancer Test (EXO-OC Test) is in development for early detection of ovarian cancer in asymptomatic women. EXO-NET has been used to enable the biomarker discovery and translation of this novel exosomal test from bench-to-clinic to help save women's lives. When these high performing EXO-NET®-isolated biomarkers were combined in 10-fold cross validated machine learning algorithms overall test accuracy exceeded 94%. When test specificity was set at 96%, sensitivity was 92% for all stages of disease and 91% for Stage I alone.

INOVIQ has secured the option for an exclusive worldwide license to develop and commercialise the exosome-based early detection test for ovarian cancer from UniQuest. UQ's commercialisation company UQ, was previously awarded a $800k grant from the Ovarian Cancer Research Fund and a $2.7m Medical Research Future Fund (MRFF) grant to develop the EXO-OC test due to the significant unmet need for earlier detection of ovarian cancer.

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[1] Cancer Today (IARC) 2020: https://gco.iarc.fr/
[2] ACS 2021: https://www.cancer.org/cancer/ovarian-cancer/detection-diagnosis-staging/detection.html
[3] SEER 18 2011-2017: https://seer.cancer.gov/statfacts/html/ovary.html
[4] https://www.cancer.org/cancer/ovarian-cancer/detection-diagnosis-staging/detection.html
[5] Ovarian Cancer Diagnostics Market Size, Share, Trends | Forecast 2032 (www.acumenresearchandconsulting.com)

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