EXO-OVARIAN CANCER SCREENING PROGRAM COMPLETES SERUM EQUIVALENCE STUDY

- **Serum equivalence study confirms EXO-NET isolates extracellular vesicles (EVs) from both plasma and serum samples - enables access to large ovarian cancer serum biobanks for further research**
- **Previously identified exosomal biomarkers were also found in long-term biobanked plasma and serum samples (14-17 years) but displayed greater variability than in recently collected plasma samples (1-5 years)**
- **It was concluded that long-term biobanked serum samples were not suitable for exosome-based biomarker discovery and validation**
- **Further development of EXO-OC test is now expected to commence in H2 FY24, upon sourcing suitable samples for further EXO-OC development and validation**

Melbourne, Australia, 9 August 2023: INOVIQ Limited (ASX:IIQ) (**INOVIQ** or the **Company**), a developer of next-generation exosome solutions and precision diagnostics, today announced results from an equivalence study to evaluate exosome-based biomarkers and performance of the EXO-OC test algorithm in 250 paired plasma and serum samples.

Background

- Proof-of-concept studies conducted by Associate Professor Carlos Salomon's group at The University of Queensland (UQ) previously demonstrated that a potential exosome-based ovarian cancer test delivered over 90% accuracy for the detection of early-stage (stages I and II) ovarian cancer in over 450 plasma samples from asymptomatic women. The EV-based protein and miRNA biomarkers were discovered in plasma samples using Size Exclusion Chromatography (SEC) to isolate EVs.
- INOVIQ previously announced that a 97-plasma sample EXO-NET evaluation study (OC97/OC-ED003) was completed by UQ (ASX: 13 December 2022). The results confirmed the utility of INOVIQ's fast, efficient and scalable EXO-NET technology for exosome biomarker discovery and development of an EV-based ovarian cancer screening test with over 90% accuracy for the detection of early-stage ovarian cancer in plasma samples.
- To date, the exosome-based Ovarian Cancer Test (EXO-OC) has been developed using plasma samples (stored for 1-5 years). To determine if long-term biobanked serum samples could be used for further development and evaluation of the test, UQ conducted an equivalence study in 250 paired serum and plasma samples (OC250/OC-ED004).
- Previous studies have reported degradation of non-exosome biomarkers during long-term storage, however, no data were available on the effect of long-term storage (up to 17 years) on exosomal biomarkers. Therefore, before proceeding to a large cohort study, it was imperative to confirm: (i) that EXO-NET performs similarly in both plasma and serum (as many of the large biobanks are serum samples); and (ii) exosome biomarkers are not affected by long-term storage.
- The objectives of OC-ED004 were to evaluate: (i) the presence of previously identified exosome-based protein and miRNA biomarkers in paired plasma and serum samples that had been stored for 14-17 years; and (ii) the performance of these biomarkers to discriminate between ovarian cancer case and control samples including in multivariate models.

Results

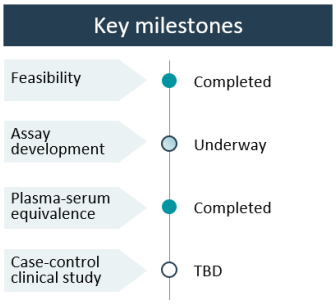
- Previously identified exosomal plasma protein and miRNA biomarkers were successfully identified in both serum and plasma samples.
- In samples from this long-term biobank (samples stored for 14-17 years), the exosomal biomarkers did not effectively discriminate between case and control.
- Further analysis identified differences between long- and short-term stored samples. Increased sample haemolysis, lipid concentration, EV concentration and particle size were associated with long-term storage.
- The OC-ED004 study has provided critical data that informs the ongoing development of the EXO-OC test establishing that biobanked samples stored for 14-17 years were not suitable for exosome-based biomarker discovery and validation.

CSO Dr Gregory Rice said: "*The OC-ED004 study provided invaluable findings for the further development of the EXO-OC test. Prior to commencing a large cohort study of biobanked serum samples it was imperative to establish the equivalence of serum and effects of long-term storage. The study identified significant differences in the behaviour of long-term storage samples when compared to recently collected samples. These differences are sufficient to necessitate the use of recently collected samples for further test development and validation. INOVIQ intends to work with UQ to identify a suitable sample cohort to progress test development*."

CEO Dr Leearne Hinch said: "*The equivalence study successfully confirmed the performance of our EXO-NET pan-exosome capture tool for EV isolation in both plasma and serum samples. However, the study showed that long-term biobanked samples were not suitable for exosomal biomarker evaluation. INOVIQ now plans to source suitable plasma samples to inform further development and validation of the EXO-OC test. Underpinned by strong early data, we look forward to further advancing the EXO-OC program to fill a significant market gap, given there is currently no recommended screening test for ovarian cancer in asymptomatic women.*"

EXO-OC program next development steps

The next phase of development for the EXO-OC test is to undertake a planned retrospective case-control (1:2) clinical study (OC-ED005). The study expects to be in up to 1000-samples and evaluate performance of the EXO-OC Test to discriminate ovarian cancer across all stages. Upon collection of suitable samples, the study is expected to commence in H2 FY24 and complete within 12-months.



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Authorised by the Company Secretary, Mark Edwards.

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ABOUT INOVIQ LTD

INOVIQ Ltd (ASX:IIQ) (**INOVIQ**) is developing and commercialising next-generation exosome solutions and precision diagnostics to improve the diagnosis and treatment of cancer and other diseases. The Company has commercialised the EXO-NET pan-exosome capture tool for research purposes and the hTERT test as an adjunct to urine cytology testing for bladder cancer. Our cancer diagnostic pipeline includes blood tests in development for earlier detection and monitoring of ovarian, breast and other cancers. For more information on INOVIQ, see www.inoviq.com.

ABOUT OVARIAN CANCER

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 is expected to reach US$1.8 billion by 2026.[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 is being used to enable the biomarker discovery and translation of this novel exosomal test from bench-to-clinic to help save women's lives. INOVIQ has secured the option for an exclusive worldwide license to develop and commercialise the exosome-based early detection test for ovarian cancer from The University of Queensland (UQ) (ASX: 1 April 2022). UQ was awarded 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.[6]

FORWARD LOOKING STATEMENTS

This announcement contains certain 'forward-looking statements' within the meaning of the securities laws of applicable jurisdictions. Forward-looking statements can generally be identified by the use of forward-looking words such as 'may', 'should', 'expect', 'anticipate', 'estimate', 'scheduled' or 'continue' or the negative version of them or comparable terminology. Any forecasts or other forward-looking statements contained in this announcement are subject to known and unknown

[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] https://www.grandviewresearch.com/industry-analysis/ovarian-cancer-diagnostics-market
[6] The UQ EV Ovarian Cancer project has previously received grant funding support from the Ovarian Cancer Research Foundation

risks and uncertainties and may involve significant elements of subjective judgment and assumptions as to future events which may or may not be correct. There are usually differences between forecast and actual results because events and actual circumstances frequently do not occur as forecast and these differences may be material. The Company does not give any representation, assurance or guarantee that the occurrence of the events expressed or implied in any forward-looking statements in this announcement will actually occur and you are cautioned not to place undue reliance on forward-looking statements.