

# INOVIQ AND UQ EXPAND COLLABORATION TO DEVELOP WORLD-FIRST EXOSOME-BASED OVARIAN CANCER SCREENING TEST

- INOVIQ and The University of Queensland (UQ) expand collaboration to develop a world-first exosome-based ovarian cancer screening test
- UQ to develop exosome-based blood test for the earlier detection of ovarian cancer under a \$2.7m Medical Research Future Fund (MRFF) grant
- INOVIQ to provide its EXO-NET® technology for fast, accurate and scalable exosome isolation in thousands of blood samples
- INOVIQ has the exclusive option to license rights to the development and commercialisation of UQ's exosome-based early detection test for ovarian cancer to improve women's health outcomes and help save lives

**Melbourne, Australia, 1 April 2022:** INOVIQ Limited (ASX:IIQ) (**INOVIQ** or the **Company**) is excited to announce that it has expanded its collaboration with The University of Queensland (UQ) to develop a world-first exosome-based ovarian cancer screening test.

#### Using exosomes as a source of accurate biomarkers for cancer

Exosomes are a type of extracellular vesicle (EV) that are small particles (around 30-150 nm) released by most cells into biofluids such as blood, urine and saliva. Exosomes contain different types of bioactive molecules such as DNAs, RNAs, proteins and lipids that convey important information about their parent cell that can be used for the identification of biomarkers, diagnosis and treatment of disease.

INOVIQ's EXO-NET technology efficiently captures exosomes from the blood to enable development of multiomic diagnostic tests that combine the multiple biomarkers in an algorithm for the earlier and more accurate detection of various diseases such as cancer, inflammatory, metabolic and neurodegenerative diseases.

## Background – compelling initial data from UQ

Previously, INOVIQ announced (ASX: 28 July 2021) that researchers from UQ identified and validated exosomal protein and micro RNA (miRNA) biomarkers that combined in the OCRF-7 algorithm<sup>1</sup> showed over 90% accuracy to detect Stages 1 and 2 ovarian cancer in an independent 500-sample retrospective case-control study.

Additionally, UQ conducted an initial evaluation of INOVIQ's patented EXO-NET pan-exosome capture product compared to UQ's in-house size exclusion chromatography method for isolation of the relevant exosomal biomarkers. They concluded that EXO-NET provided simple and rapid capture of the exosomal biomarkers with high purity and yield.

#### **Collaboration expansion**

INOVIQ and UQ have now expanded their collaboration to further evaluate EXO-NET and, if successful, UQ will use EXO-NET technology in the development of the UQ OCRF-7 ovarian cancer test.

The collaborative partnership is under an Umbrella Research and Option Agreement that allows the parties to put in place specific project agreements over time when required for the ongoing development of the UQ OCRF-7 ovarian cancer test. INOVIQ worked with UQ's commercialisation company UniQuest to negotiate this agreement which provides INOVIQ with an exclusive option to license UQ's intellectual property in the OCRF-7 ovarian cancer test.

<sup>&</sup>lt;sup>1</sup> Earlier research contributing to the OCRF-7 diagnostic test was supported by a grant from the Ovarian Cancer Research Foundation.

The first project involves the further evaluation and use of EXO-NET to identify additional informative biomarkers for inclusion in UQ's OCRF-7 ovarian cancer test. INOVIQ will provide its EXO-NET product, in-kind expertise, and research funding. This project is expected to be completed within 12 weeks.

On the basis of a successful outcome, EXO-NET will then be used for exosome isolation in the ongoing development of UQ's exosome-based earlier detection test for ovarian cancer. This includes UQ's translational research project funded by the Australian Government's Medical Research Future Fund (MRFF), under which INOVIQ will contribute its EXO-NET exosome capture product, in-kind expertise and pay patent costs.

Should INOVIQ request UQ to undertake any additional translational research and development then it will be enabled through the Umbrella Research and Option Agreement.

"There remains a clear unmet need for the earlier detection of ovarian cancer" said Dr Dean Moss, Chief Executive Officer of UniQuest. "We are extremely pleased to collaborate with Australian-based company INOVIQ to combine our innovative technologies and expertise in biomarker discovery, exosome isolation and clinical translation to advance UQ's promising new exosome-based test for ovarian cancer towards key development milestones."

#### Medical Research Future Fund (MRFF) grant and project

The University of Queensland has been awarded a \$2.7 million competitive grant under the government's Medical Research Future Fund (MRFF) for a project titled '*Implementing a Multivariate Index Assay for the Earlier Detection of Ovarian Cancer*' (application 2009502). The MRFF Project will be led by UQ's <u>Associate</u> <u>Professor Carlos Salomon Gallo</u> from UQ's Centre for Clinical Research as the lead Chief Investigator, involves multiple participating institutions (including University College London and Australian National University) and has a duration of four years. INOVIQ's Chief Scientific Officer (CSO), Professor Greg Rice, is also a Chief Investigator on this MRFF Project.



Assoc Prof Carlos Salomon Gallo

Extracellular vesicle (EV) isolation (including of exosomes) is a key element of MRFF Project. Associate Professor Carlos Salomon Gallo said: "The use of a scalable exosome isolation tool such as INOVIQ's EXO-NET product is critical to enable the commercialisation of routine exosome-based tests that can be used in pathology laboratories worldwide."

The MRFF Project has multiple phases including multiomic biomarker isolation and analysis, assay and algorithm development for a Multivariate Index Assay (MIA), analytical validation and clinical validation of the test for the earlier detection of ovarian cancer. The clinical validation study is planned to be performed at UQ using EXO-NET to isolate exosomes from thousands of blood samples collected from the world's largest ovarian cancer screening trial (UK Collaborative Trial of Ovarian Cancer Screening). These activities will be conducted under ISO 13485:2016 requirements for the design, development and manufacture of medical devices.

INOVIQ CSO, Professor Greg Rice said, "EXO-NET enables the targeted isolation of exosomes and the enrichment of clinically-relevant biomarkers of disease onset and progression. These exosomal biomarkers can be developed as a multivariate index assay using an algorithm in a blood test to deliver increased sensitivity and specificity for earlier and more accurate detection of ovarian cancer. Ovarian cancer often progresses without overt clinical symptoms until late-stage disease. The exosome-based ovarian cancer test being developed by UQ and commercialised by INOVIQ has the potential to provide women with more timely information about their health and clinicians with a level of medical surveillance not previously available."

INOVIQ CEO, Dr Leearne Hinch said, "There is currently no accurate and reliable blood test available for screening ovarian cancer. The combination of INOVIQ's EXO-NET technology to capture exosomes and UQ's novel exosomal biomarkers is expected to allow significantly improved earlier and more accurate detection of ovarian cancer. INOVIQ is excited to collaborate with Associate Professor Salomon Gallo's team at UQ to develop and commercialise this world-first exosome-based ovarian cancer screening test to improve women's health outcomes and help save lives."

Authorised by the Company Secretary, Tony Di Pietro.

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# COMPANY CONTACTS

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# ABOUT INOVIQ LTD

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

## ABOUT UNIQUEST AND THE UNIVERSITY OF QUEENSLAND (UQ)

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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. Notable successes include the blockbuster cervical cancer vaccine Gardasil® and start-up companies Spinifex Pharmaceuticals Inc and Inflazome Ltd, which were acquired in two of the largest university start-up exits in Australian history.

# ABOUT OVARIAN CANCER AND THE NEED FOR A SCREENING TEST

Ovarian cancer (OC) is the world's deadliest gynaecological cancer, the eighth most common cancer and eighth leading cause of cancer-related deaths in women worldwide. Globally, there were over 314,000 new cases and 207,000 deaths 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.<sup>2</sup> 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.<sup>3</sup>

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%.<sup>4</sup> 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.<sup>5</sup> *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\$1.9 billion in 2026.<sup>6</sup>

#### 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 forwardlooking 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 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

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<sup>&</sup>lt;sup>2</sup> Cancer Today (IARC) 2020: <u>https://gco.iarc.fr/</u>

<sup>&</sup>lt;sup>3</sup> ACS 2021: <u>https://www.cancer.org/cancer/ovarian-cancer/detection-diagnosis-staging/detection.html</u>

<sup>&</sup>lt;sup>4</sup> SEER 18 2011-2017: <u>https://seer.cancer.gov/statfacts/html/ovary.html</u>

<sup>&</sup>lt;sup>5</sup> https://www.cancer.org/cancer/ovarian-cancer/detection-diagnosis-staging/detection.html

<sup>&</sup>lt;sup>6</sup> https://www.grandviewresearch.com/industry-analysis/ovarian-cancer-diagnostics-market

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.