EXCELLENT CLINICAL DATA FOR SUBB2M/CA15-3 BREAST CANCER TEST

- **INOVIQ's SubB2M/CA15-3 breast cancer test detects all-stages of breast cancer with excellent accuracy (87%), sensitivity (81%) and specificity (93%)**
- **The results of a comprehensive 483-sample case-control study established that INOVIQ's SubB2M/CA15-3 blood test significantly outperformed a leading approved CA15-3 test, demonstrating an area under the curve (AUC) of 0.93 compared to 0.70**
- **INOVIQ is finalizing its planned breast cancer monitoring study and advancing discussions with potential partners and Key Opinion Leaders (KOL's) for its SubB2M platform and tests**

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Melbourne, Australia, 27 June 2023: INOVIQ Limited (ASX:IIQ) (**INOVIQ** or the **Company**), a developer of next-generation exosome solutions and precision diagnostics, is pleased to announce excellent results from an independent clinical validation study of its SubB2M/CA15-3 test for breast cancer detection. The study showed high accuracy (87%), sensitivity (81%), and specificity (93%) for INOVIQ's SubB2M test, outperforming a leading approved CA15-3 test.

CEO Dr Leearne Hinch said: "*The outstanding results from this independent clinical validation study of our SubB2M breast cancer test represent a major milestone for INOVIQ. Our SubB2M/CA15-3 blood test detected all-stages of breast cancer with 81% sensitivity and 93% specificity, outperforming a leading CA15-3 test. These positive results support the commercial potential of our simple, cost-effective SubB2M/CA15-3 test for screening and monitoring of breast cancer.*

INOVIQ intends to present these data and our development plans to potential partners and KOLs to advance commercial discussions for its SubB2M/CA15-3, SubB2M/CA125 and SubB2M multi-cancer tests."

Background to SubB2M technology and SubB2M/CA15-3 test

INOVIQ's disruptive **SubB2M technology** is an engineered protein that detects the pan-cancer biomarker **Neu5Gc**, found in multiple human cancers. SubB2M tests are designed to enhance the sensitivity, specificity and clinical utility of existing tumour marker tests routinely used for cancer detection and monitoring, such as CA15-3 for breast cancer, CA125 for ovarian cancer, PSA for prostate cancer and CA19.9 for pancreatic cancer.[1]

CA15-3 tumour marker tests are routinely used to monitor breast cancer treatment response and disease recurrence. However, existing CA15-3 tests have inadequate sensitivity and specificity for early-stage detection and are commonly used as an adjunct to other diagnostic tests for monitoring. The SubB2M/CA15-3 test is initially being developed as an improved monitoring test for breast cancer.

INOVIQ engaged US-based contract research organisation, ResearchDx, to undertake assay development and validation of its SubB2M tests (ASX: 5 April 2022). Positive results were previously reported from the analytical validation of the SubB2M/CA15-3 test, demonstrating 78% sensitivity and 80% specificity for detection of breast cancer (ASX: 8 February 2023). The SubB2M/CA15-3 test subsequently underwent further optimisation to improve sensitivity and specificity prior to commencing clinical validation.

SubB2M/CA15-3 test clinical validation study method, results and conclusion

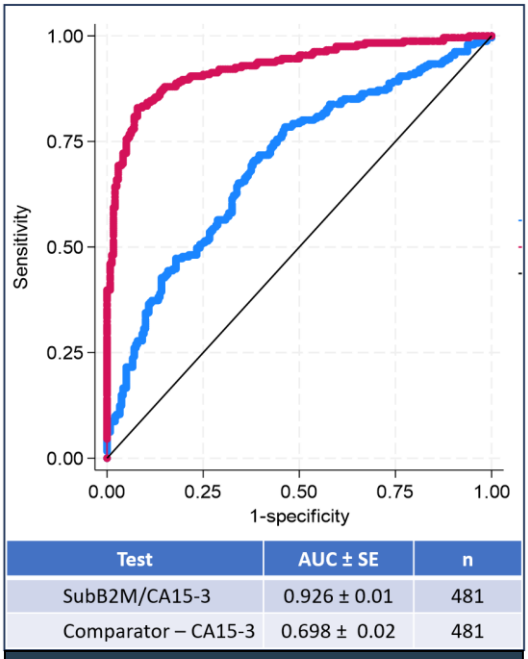
The objectives of this 483-sample, case-control, clinical validation study were to: 1) evaluate the clinical performance of the SubB2M/CA15-3 test across all stages of breast cancer compared to healthy controls; and 2) to compare the performance of the SubB2M/CA15-3 test to a leading approved CA15-3 test in the same samples in a clinical laboratory setting.

The results demonstrated that INOVIQ's SubB2M/CA15-3 breast cancer test provides more accurate detection of breast cancer across all stages. INOVIQ's test demonstrates overall sensitivity and specificity of 81% and 93%, compared to an approved CA15-3 test of 37% sensitivity and 88% specificity (Table 1). The SubB2M test significantly reduces misdiagnoses with lower false positive (7%) and false negative (19%) rates, in this sample set.

Table 1: SubB2M/CA15-3 and comparator CA15-3 test performance summary

Breast Cancer All Stages	SubB2M	Comparator
AUC	0.93	0.70
sensitivity	81%	37%
specificity	93%	88%
false negative rate	19%	63%
false positive rate	7%	12%
positive predictive value	92%	75%
negative predictive value	83%	58%
overall accuracy	87%	63%

The study established that INOVIQ's SubB2M/CA15-3 blood test significantly outperformed a leading approved CA15-3 test. The area under the curve (AUC) for INOVIQ's test was 0.93, compared to the Comparator test of 0.70, indicating the superior diagnostic accuracy of the SubB2M test (Figure 1).



Test	AUC ± SE	n
SubB2M/CA15-3	0.926 ± 0.01	481
Comparator – CA15-3	0.698 ± 0.02	481

Figure 1. Receiver Operating Characteristic (ROC) curves for INOVIQ's (red) and Comparator CA15-3 (blue) tests. A ROC curve is a measure of the diagnostic performance of a test. The closer to the Reference line (black) the less accurate the test. The AUC summarises the overall performance of the test (1.0 = completely accurate). The AUC of the INOVIQ test (0.93) is significantly greater that the AUC of the Comparator test (0.70, p = 0.0001), indicating superior diagnostic accuracy.

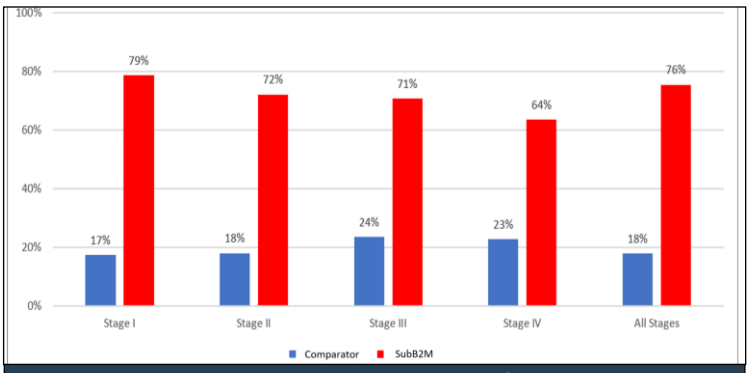


Figure 2: CA15-3 Test Sensitivity at 95% Specificity by breast cancer stage

Analysis of test sensitivity at 95% specificity by breast cancer stage, demonstrates the superior performance of the SubB2M/CA15-3 test compared to a leading CA15-3 test for detection of breast cancer across all stages, in this sample set (Figure 2). The SubB2M/CA15-3 test's performance was confirmed through logistic regression analysis, and these data support its potential use for both screening and monitoring of breast cancer.

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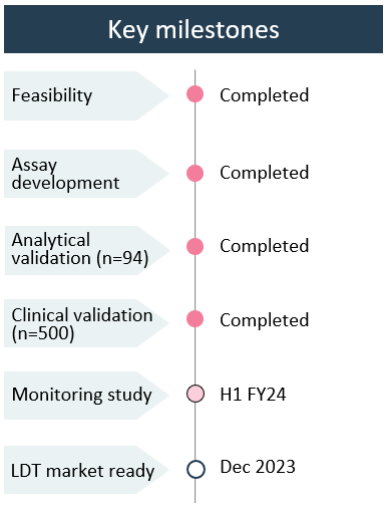
INOVIQ CSO, Dr Gregory Rice said: "*In this large clinical validation study, the SubB2M/CA15-3 test clearly outperformed a leading CA15-3 test at all cut-off points tested. Its impressive performance makes it an ideal blood test for enhancing treatment response monitoring and enabling earlier detection of disease recurrence. Having completed rigorous analytical and clinical validation, the next step involves conducting disease monitoring studies and assessing the test's impact on clinical decision-making in collaboration with KOLs and potential partners in the United States.*"

Dr Mathew Moore, Principal of ResearchDx, added: "*These outstanding data clearly improve on existing CA15-3 tumour marker tests routinely used for monitoring breast cancer. The SubB2M/CA15-3 test detects all stages of breast cancer with high accuracy, which could be a game-changer for clinicians and clinical practice for screening of undiagnosed breast cancer and in monitoring diagnosed breast cancer.*"

SubB2M CA15-3 test and next development steps

INOVIQ's next step is to conduct a **cross-sectional monitoring study** to demonstrate the superior performance of the SubB2M/CA15-3 test for treatment response and/or disease recurrence over approved CA15-3 tests.

INOVIQ is working with ResearchDx and its clinical advisors to finalise the clinical validation plan. This clinical study is expected to complete by the end of Q2 FY24, with the test then expected to be market-ready.



Other SubB2M test development plans

INOVIQ is also progressing its development plans for the **SubB2M/CA125 test** for ovarian cancer. Samples have been sourced and assay development and analytical validation studies are expected to commence in H1 FY24 and complete within 6 months. Clinical validation of this test is now expected to complete in H2 FY24.

The research-stage **SubB2M multi-cancer test** (MCT) on the Nicoya ALTO™ SPR instrument is undergoing further evaluation, with data now expected to report in Q1 FY24. Additional opportunities for development of a potential SubB2M MCT for point-of-care testing on other instrument platforms are also being assessed internally and with potential partners.

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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 SUBB2M PLATFORM

SubB2M is an engineered protein that preferentially binds to the pan-cancer biomarker Neu5Gc, found in multiple human cancers. INOVIQ is developing SubB2M blood tests for multiple uses, including monitoring breast and ovarian cancers, and for a general health panel. SubB2M may enhance the performance of existing tumour marker tests by binding to multiple Neu5Gc sites on the biomarker that amplify the signal to improve sensitivity, and by increasing the cancer specificity to reduce false positives.

ABOUT BREAST CANCER AND BREAST CANCER MONITORING

According to the World Health Organisation, breast cancer is the most common cancer globally, with 2.3m new cases, 685k deaths and 7.8m survivors (5-year prevalence) in 2020.[2] The global breast cancer diagnostics market was valued at $4.2b in 2021.[3] The intended use of the SubB2M/CA15-3 breast cancer test is as an aid for monitoring breast cancer treatment response and recurrence in women previously diagnosed with the disease. The American Society of Clinical Oncology (ASCO) 2015 guidelines recommend regular physical examination and mammography for monitoring breast cancer disease progression and recurrence.[4] Existing blood tests for serum tumour markers (CA15.3, CA 27.29 and CEA) are not sensitive or specific for breast cancer relapse, but are suggested for monitoring treatment response of women with metastatic breast cancer or follow-up in symptomatic women. There is a need for faster, more accurate and cost-effective blood tests to improve breast cancer detection and monitoring. INOVIQ's SubB2M/CA15-3 test has the potential to deliver high sensitivity and specificity for earlier detection and monitoring of breast cancer.

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 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.

[1] **Sensitivity** is the ability of a test to correctly identify women with breast cancer. **Specificity** is the ability of a test to correctly identify cancer-free women.
[2] Global Cancer Observatory: Cancer Today. Lyon, France: International Agency for Research on Cancer. Available: https://gco.iarc.fr/today, accessed [5 February 2023].
[3] Grand View Research. Breast Cancer Diagnostics Market Size, Share & Trends Analysis Report, 2021 – 2028. 2020; Available: https://www.grandviewresearch.com/industry-analysis/breast-cancer-diagnostics-market
[4] Sharma, P. Overview of the approach to metastatic breast cancer. UpToDate. 2023.

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