POSITIVE RESULTS FOR SUBB2M BREAST CANCER TEST

- **INOVIQ's SubB2M-enhanced CA15.3 breast cancer test outperforms a leading commercially available CA15.3 tumour marker test**
- **Data from a 94-serum case-control study demonstrates that INOVIQ's SubB2M-enhanced CA15.3 blood test significantly improves diagnostic performance when compared to Roche's Elecsys® CA15.3 II test**
- **INOVIQ will now conduct a larger study across all-stages of breast cancer and a monitoring study for breast cancer**

Melbourne, Australia, 8 February 2023: INOVIQ Limited (ASX:IIQ) (**INOVIQ** or the **Company**) is pleased to announce positive results from an independent retrospective case-control study to evaluate the performance of its SubB2M-CA15.3 breast cancer test across all stages of breast cancer.

CA15.3 is a tumour marker test that is commonly used in a clinical setting to monitor breast cancer treatment response and disease recurrence. By enhancing existing tumour marker tests with SubB2M, sensitivity, specificity and clinical utility are expected to be improved[1].

The objective of this 94-serum sample study was firstly, to establish that INOVIQ's SubB2M-CA15.3 test effectively discriminates between breast cancer cases and control samples, and secondly, to compare the performance of the SubB2M-CA15.3 test against Roche's Elecsys® CA15.3 II test running in a clinical service laboratory. The data showed INOVIQ's SubB2M-CA15.3 test clearly discriminated between breast cancer and healthy controls across all cancer stages (Figure 1), correctly identifying 73% (69/94) of all samples tested. When compared to Roche's Elecsys® CA15.3 II test, performed on the same set of samples, INOVIQ's SubB2M-CA15.3 test displayed superior performance with:

- AUC[2] of 0.81 vs 0.68 (Figure 2);
- lower false positive rate (21% vs 29%); and
- lower false negative rate (31.3% vs 43.8%).

The overall performance of INOVIQ's test was 69% sensitivity and 78% specificity for breast cancer across all stages, compared to 56% sensitivity and 71% specificity for the Roche test. Notably, INOVIQ's test discriminated early-stage breast cancer (Stage I and II) from healthy controls, whereas the Roche test only discriminated stage IV cancer from controls.

CSO Dr Gregory Rice said: "*These data show that INOVIQ's SubB2M-CA15.3 test discriminates breast cancer from controls across all stages and significantly outperforms the Roche test; reducing the number of samples misdiagnosed by approximately 10%. Importantly, these tests were conducted by independent US-based laboratories; SubB2M-CA15.3 by contract research organisation ResearchDx and Elecsys® CA15.3 II by a clinical pathology service laboratory. The results of this study are very promising given INOVIQ's test detects early-stage breast cancer, in contrast to Roche's test, which did not discriminate between early-stage disease and healthy.*"

CEO Dr Leearne Hinch said: "*The successful completion of this study represents a significant advance in INOVIQ's SubB2M diagnostics program. Following the steps outlined below, the SubB2M-CA15.3 test will be the first of INOVIQ's SubB2M-enhanced blood tests to be commercialised, initially as an aid for monitoring breast cancer. As Neu5Gc is a pan-cancer marker, SubB2M may be used to improve other widely used tumour marker tests.*"

Next steps for the SubB2M-CA15.3 test

The next steps in developing the SubB2M-CA15.3 test for commercialisation are:

(i) to complete a 500-sample case-control study to evidence the superior performance of the SubB2M-enhanced cancer detection tests over existing, approved and widely used tests; and

(ii) to complete a monitoring study for treatment response and disease recurrence.

Sample acquisition/collection for these studies is already underway and the SubB2M-CA15.3 test is expected to be launch-ready by a laboratory partner in December 2023.

Additionally, the assay development work completed for the SubB2M-CA15.3 test will now be applied to fast-tracking the development and validation of the SubB2M-CA125 test for **ovarian cancer** monitoring.

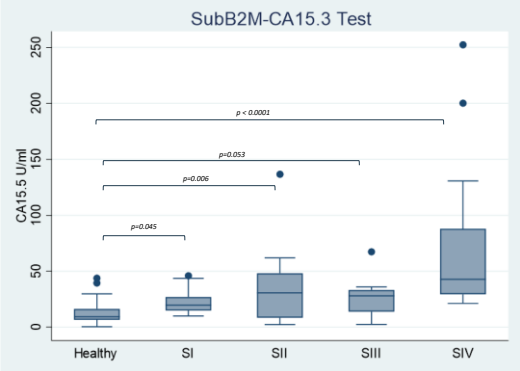

Figure 1. Serum concentrations of CA15.3 (units/ml) measured in healthy (n=46) and women with Stage I to IV (n=12 at each stage), using the INOVIQ test. The results are presented as the median and interquartile range (IQR). The whiskers extend to 1.5 x IQR. The pairwise statistical difference between the healthy group and disease stages is shown by the horizontal line.

About INOVIQ's SubB2M platform

SubB2M is an engineered protein that preferentially binds to the pan-cancer biomarker Neu5Gc. INOVIQ is developing SubB2M-enhanced 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 and improve sensitivity, and by increasing the cancer specificity to reduce false positives.

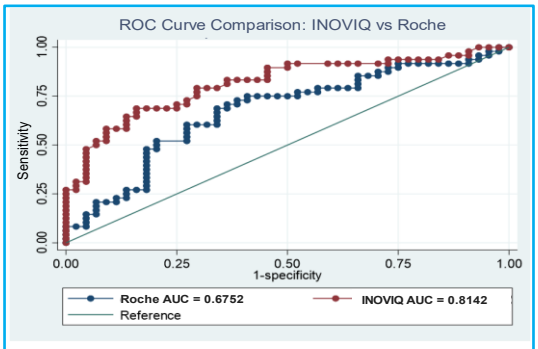

Figure 2. Receiver Operating Characteristic (ROC) curves for INOVIQ's and Roche's CA15.3 tests. A ROC curve is a measure of the diagnostic performance of a test. The closer to the Reference line the less accurate the test. The area under the curve (AUC) summarises the overall performance of the test (1.0 = completely accurate). The AUC of the INOVIQ test (0.81) is significantly greater that the AUC of the Roche test (0.68, p = 0.0003).

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.[3] The global breast cancer diagnostics market was valued at $4.2b in 2021.[4] The intended use of the SubB2M breast cancer test is as an aid for monitoring breast cancer in women that have been diagnosed with breast cancer. The American Society of Clinical Oncology (ASCO) 2015 guidelines recommend regular physical examination and mammography for monitoring breast cancer disease progression and recurrence.[5] 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. Roche's Elecsys CA15.3 II test is used to monitor breast cancer treatment response and disease recurrence. At 95% specificity, Roche's test has a sensitivity of 7% for stage I, 11% for stage II, 39% for stage III and 78% sensitivity for stage IV disease, and 81% for recurrent disease.[6] There is a need for faster, more accurate and cost-effective blood tests to improve breast cancer detection and monitoring.

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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 capture tools 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.

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.

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[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] A Receiver Operating Characteristic (ROC) curve is method of estimating the performance of a test to classify samples as diseased or healthy. The area under the ROC curve (AUC) represents how well the test can correctly discriminate between case and control samples; the higher the AUC, the better the test. In this study, the AUC was estimated using boosted logistics regression analysis, with 10-fold cross-valuation.
[3] Global Cancer Observatory: Cancer Today. Lyon, France: International Agency for Research on Cancer. Available: https://gco.iarc.fr/today, accessed [5 February 2023].
[4] 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
[5] Sharma, P. Overview of the approach to metastatic breast cancer. UpToDate. 2023.
[6] P. Stieber, R. Molina, D. W. Chan, H. A. Fritsche, R. Beyrau, J. M. Bonfrer, et al. Clinical evaluation of the Elecsys CA 15-3 test in breast cancer patients. Clin Lab 2003;49(1-2): 15-24. Available: https://www.ncbi.nlm.nih.gov/pubmed/12593471