

22 February 2024

## ASX Announcement

# INOVIQ DETECTS 19% MORE BREAST CANCERS THAN LEADING TEST

INOVIQ Limited (ASX:IIQ or **INOVIQ**) is excited to announce the successful completion of its breast cancer study.

In a 2023 clinical validation study (n=483), INOVIQ's SubB2M/CA15-3 test detected over 80% of breast cancers across all stages with 93% specificity. The recently completed monitoring study showed INOVIQ's test detected breast cancer across key cancer subtypes, correctly identified 19% more breast cancers than a leading approved test and was effective for monitoring breast cancer. The Company intends to use these results to attract a partner to speed up the commercialisation of the test.

### Breast Cancer study

The aim of the study was to demonstrate the performance of INOVIQ's test for detection of breast cancer subtypes and post-treatment monitoring compared with an FDA cleared test (Roche Elecsys). Serum samples (n=277) were provided by The University of Queensland and analysed by US CRO ResearchDx.

The cancer subtype leg of the study used 159 pre-treatment serum samples from women diagnosed with breast cancer. The test detected breast cancer across all key subtypes (HR+, HER2+ and TNBC)<sup>1</sup>. Importantly, the test outperformed the FDA approved test by correctly identifying 19% more histologically-confirmed breast cancers.

In the monitoring leg of the study, CA15-3 concentrations were assessed in serum obtained from 12 women before treatment and then at up to 5 subsequent time points post-treatment. The study established equivalence between INOVIQ's test and the comparator test for monitoring breast cancer.

### Next steps

INOVIQ now intends to present its SubB2M/CA15-3 test data package to potential partners and key opinion leaders to secure a partner in the US to speed the commercialisation of the test and revenue generation.

INOVIQ will also sponsor a larger in-clinic trial to gain further data to substantiate the performance of its test for monitoring breast cancer treatment responses and to facilitate clinical adoption. INOVIQ is in discussions with CROs to undertake a larger study.

CEO Dr Leearne Hinch said: *“The SubB2M/CA15-3 test is designed to be an aid for monitoring breast cancer. The results of this study are powerful having demonstrated the test detected different breast cancer subtypes, correctly identified 19% more breast cancers than a leading CA15-3 test and was effective for breast cancer monitoring.”*

Chairman David Williams said: *“These are exciting results because this simple, accurate and affordable test could provide a more effective test for detecting and monitoring breast cancers, and lead to better patient management. The ability to identify cancer subtypes could be a game changer. In the meantime, we will use these results to quickly pursue alliances and partnerships to bring our technology to market.”*

*Authorised for release by the Company Secretary, Mark Edwards.*

### Further Information

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## ABOUT INOVIQ LTD

INOVIQ Ltd (ASX:IIQ) 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, visit [www.inoviq.com](http://www.inoviq.com).

## BACKGROUND TO SUBB2M TECHNOLOGY AND SUBB2M/CA15-3 TEST

INOVIQ's disruptive **SubB2M technology** is an engineered protein that detects the cancer biomarker **neu5Gc**<sup>2</sup> found in multiple human cancers. SubB2M enhances the sensitivity and specificity of protein tumour markers by binding to multiple neu5Gc sites and reducing false positives from non-cancers. The SubB2M/CA15-3 test is designed to be an aid for monitoring breast cancer treatment response and recurrence.

**CA15-3**<sup>3</sup> tumour marker tests are routinely used<sup>3</sup> 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 a clinical validation of the SubB2M/CA15-3 test, demonstrating 81% sensitivity and 93% specificity for detection of breast cancer across all stages (ASX: 29 June 2023).

## 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.<sup>4</sup> The global breast cancer diagnostics market was valued at US\$4.3b in 2022 and is expected to reach US\$7.7b by 2030.<sup>5</sup> 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 disease. The American Society of Clinical Oncology (ASCO) 2015 guidelines recommend regular physical examination and mammography for monitoring breast cancer disease progression and recurrence.<sup>6</sup> Existing blood tests for serum tumour markers (CA15.3, CA 27.29 and CEA) are not sensitive or specific for breast cancer recurrence but are suggested for monitoring treatment response of women with metastatic breast cancer. 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 detection and monitoring of breast cancer.

<sup>1</sup> HR+ = Hormone Receptor positive; HER2+ = Human Epidermal growth factor Receptor 2 (HER2) positive; TNBC = Triple-Negative Breast Cancer (TNBC)

<sup>2</sup> neu5Gc = the sialic acid, N-glycolylneuraminic acid

<sup>3</sup> CA15.3 = Cancer Antigen 15.3 biomarker used as an aid for monitoring breast cancer treatment response

<sup>4</sup> Global Cancer Observatory: Cancer Today. Lyon, France: International Agency for Research on Cancer. Available: <https://gco.iarc.fr/today>, accessed [5 February 2023].

<sup>5</sup> Grand View Research. Breast Cancer Diagnostics Market Size, Share & Trends Analysis Report, 2023 – 2030. 2020; Available: <https://www.grandviewresearch.com/industry-analysis/breast-cancer-diagnostics-market>

<sup>6</sup> Sharma, P. Overview of the approach to metastatic breast cancer. UpToDate. 2023.