ASX Announcement
1 April 2025

neuCA15-3 DIAGNOSTIC PERFORMANCE PUBLISHED IN BREAST CANCER RESEARCH AND TREATMENT

- **neuCA15-3 diagnostic performance published in international peer reviewed journal *Breast Cancer Research and Treatment***
- **neuCA15-3 test outperforms FDA-approved CA15-3 breast cancer monitoring test**
- **Potential to be further developed for earlier detection of breast cancer in combination with other biomarkers**
- **Important milestone supporting partnering and commercialisation of neuCA15-3 test**

INOVIQ Limited (ASX: IIQ) is pleased to announce its scientific paper titled 'Improved breast cancer diagnosis using a CA15-3 capture antibody-lectin sandwich assay' has been accepted for publication in international peer reviewed journal *Breast Cancer Research and Treatment*. The pre-print article is linked here, and the abstract is provided in the appendix.

The paper describes the methods and results from case: control studies showing that INOVIQ's neuCA15-3 test delivered superior diagnostic performance for breast cancer compared to the existing FDA-approved Roche Elecsys CA15-3 II test. The overall accuracy of the neuCA15-3 test was 81% compared to 55% for the comparator test.

The paper received positive feedback from reviewers regarding the enhanced diagnostic performance of the neuCA15-3 assay and its potential use with additional biomarkers for early detection of breast cancer. NeuCA15-3 had a sensitivity of 69% at 95% specificity for stage I & II breast cancers, which compares favourably to mammography.

CSO Prof Greg Rice and corresponding author commented: "*Peer-reviewed publication of data that directly underpins and aligns with product development provides evidence of scientific rigor, credibility, and transparency for stakeholders. This publication represents an important milestone for INOVIQ. It summarises work completed to date to deliver a more effective breast cancer test using our SubB2M technology. In a head-on comparison with a routinely used FDA-approved CA15-3 breast cancer test, the neuCA15-3 test significantly outperformed the existing test in correctly identifying breast cancer across all stages. Notably, the neuCA15-3 test was effective in detecting early-stage breast cancer. Based on these exciting results, we plan to further evaluate the test for earlier detection of breast cancer by combining it with other cancer biomarkers and implementing the test on existing pathology instruments*."

CEO Dr Leearne Hinch said: *"Existing CA15-3 tests are approved for monitoring breast cancer treatment response and disease recurrence. However, CA15-3 tests have poor sensitivity for early-stage breast cancer and lack cancer specificity, so they are mostly used in the metastatic setting. In contrast, our improved neuCA15-3 test can detect early-stage disease and is cancer specific, providing an opportunity for further development as a multimarker test for early breast cancer detection. INOVIQ is committed to developing better diagnostic solutions for detection and monitoring of breast and ovarian cancers to improve women's health outcomes."*

The next steps to commercialise the neuCA15-3 test involve completing transfer to a bead-based chemiluminescent assay compatible with autoanalyzer platforms, conducting an in-clinic breast cancer monitoring study, and securing a partner for commercialisation.

Authorised by the Company Secretary, Mark Edwards.

FURTHER INFORMATION

Dr Leearne Hinch
Chief Executive Officer
E lhinch@inoviq.com
M +61 400 414 416

David Williams
Chairman
E dwilliams@kidder.com.au
M +61 414 383 593

ABOUT INOVIQ LTD

INOVIQ Ltd (ASX:IIQ) is a biotechnology company pioneering next-generation diagnostics and therapeutics for cancer. INOVIQ has commercialised its fast, efficient and scalable EXO-NET exosome isolation technology for biomarker discovery and diagnostics development, and the hTERT test as an adjunct test for bladder cancer. The company is advancing clinical-stage diagnostics for detection and monitoring of ovarian and breast cancers, and early-stage exosome therapeutics for solid tumours. For more information on INOVIQ, visit www.inoviq.com.

ABSTRACT

The abstract of the pre-print paper[1] is provided below.

Improved breast cancer diagnosis using a CA15-3 capture antibody-lectin sandwich assay

S. Nikseresht[1] · L. K. Shewell[2] · C. J. Day[2] · M. P. Jennings[2] · H. Chittoory[3] · A. E. McCart Reed[3] · P. T. Simpson[3] · S. R. Lakhani[3,4] · R. Nabiee[5] · M. Moore[5] · R. Khanabdali[1] · L. M. Hinch[1] · G. E. Rice[1,3]

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Abstract

Purpose This study aims to test the hypothesis that an enzyme-linked antibody-lectin sandwich assay for a glycovariant of CA15-3 can deliver better diagnostic performance, defined by classification accuracy, sensitivity and specificity, for breast cancer compared to an existing FDA-approved CA15-3 test.

Methods A genetically engineered lectin (SubB2M) that specifically binds N-glycolylneuraminic acid (Neu5Gc) was used as a detection reagent in a CA15-3 capture antibody-lectin sandwich (neuCA15-3) assay. In a case: control cohort equivalence study the classification accuracy for the neuCA15-3 assay was determined and compared to an FDA-approved CA15-3 IVD test (Elecsys CA15-3 II, Roche Diagnostics).

Results Classification accuracy and AUC for neuCA15-3 were 81% and 0.886 ± 0.015 (standard error, $n = 567$) and for Elecsys CA15-3 II, 55% and 0.642 ± 0.023 ($n = 558$), respectively. At a threshold cut-off serum concentration of 23.6 units/ml, overall breast cancer classification accuracy of the neuCA15-3 was 81% (compared to 55% for the comparator assay, $p < 0.001$). At 95% specificity, the sensitivity of the neuCA15-3 assay was 69.5%, significantly greater than the comparator assay (11.9%, $p < 0.001$). neuCA15-3 concentrations did not vary significantly with breast cancer receptor subtype or comorbidities tested.

Conclusions The diagnostic performance of neuCA15-3 was substantially improved by specifically targeting both a CA15-3 protein epitope and a pan-cancer glycan (Neu5Gc) epitope (the specific binding target of SubB2M). The reporter signal generated depends on the colocalization of the cancer antigen protein epitope and the aberrant sialylation of the protein, thus increasing the assay specificity. The presence of multiple Neu5Gc lectin-binding sites per glycoprotein molecule increases signal generation and assay sensitivity. The inclusion of additional cancer biomarkers in a multivariate index assay format may further increase diagnostic performance for breast cancer.

[1] Nikseresht S *et al*. **Improved breast cancer diagnosis using a CA15-3 capture antibody-lectin sandwich assay**. *Breast Cancer Res Treat* (2025). https://doi.org/10.1007/s10549-025-07672-z