ASX Announcement

5 December 2024

INOVIQ COMPLETES DISEASE SPECIFICITY TESTING FOR BREAST CANCER

INOVIQ Limited (ASX:IIQ or **INOVIQ**) is pleased to announce the successful completion of disease specificity testing for breast cancer. The INOVIQ blood test is a simple, accurate and affordable immunoassay developed using a monoclonal antibody, widely used by diagnostic companies, combined with INOVIQ's SubB2M detection reagent. The hybrid test specifically detects CA15-3 produced by cancer cells, improving cancer detection and potentially reducing false positives.

The test has now been analytically and clinically validated to detect breast cancer across all stages (81% sensitivity and 93% specificity), key breast cancer types and subtypes. Importantly, the test is effective for breast cancer monitoring.

The purpose of this study was to show that the neuCA15-3 test was positive and specific for cancer and had low false positives for non-cancer diseases. CA15-3 levels were measured in serum samples obtained from healthy individuals and patients with breast cancer or other non-cancer diseases where CA15-3 could be elevated, including endometriosis, rheumatoid arthritis, Crohn's disease and type II diabetes. The test showed positive results for breast cancer, with the average CA15-3 concentration being five-fold greater than that observed in healthy individuals. The results were negative for 97.4% of non-breast cancer samples, confirming the specificity for breast cancer.

The same samples were also tested by an independent accredited pathology laboratory using a leading FDA-approved comparator CA15-3 test. Average CA15-3 concentrations were not significantly different between healthy and non-breast cancer patients for the comparator, indicating the superiority of the INOVIQ test.

CEO Leearne Hinch said: "*The test is being developed as an LDT for the US market initially. Demonstrating the specificity of neuCA15-3 for breast cancer detection completes another component of the test validation. The next step towards commercialising the neuCA15-3 test is to transfer and optimise the test on a system compatible with high-throughput commercial diagnostic instruments*."

Chairman David Williams added: "The aim is *to demonstrate that our SubB2M technology can be used as a detection reagent to enhance the performance of multiple existing cancer biomarker tests, including CA125, HE4, PSA and others*."

The next steps to commercialise the test include:

- Publication of a scientific paper on the neuCA15-3 test in a peer-reviewed journal to support partnering discussions;
- Transferring the test to an assay for implementation on a high-throughput instrument platform;
- Undertaking an in-clinic Breast Cancer monitoring study to support clinical adoption of the test; and
- Securing an accredited laboratory partner in the US for commercialisation of the test as a Laboratory Developed Test.

Authorised for release by the Company Secretary, Mark Edwards.

FURTHER INFORMATION

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ABOUT INOVIQ LTD

INOVIQ Ltd (ASX:IIQ) is a biotechnology company developing 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.

BACKGROUND TO SUBB2M TECHNOLOGY AND NEU-CA15-3 TEST

INOVIQ's **SubB2M technology** is an engineered protein that detects the cancer biomarker **neu5Gc**[1] 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 neuCA15-3 test is designed to be an aid for monitoring breast cancer treatment response and recurrence.

CA15-3[2] tumour marker tests are routinely used to monitor breast cancer treatment response and disease recurrence. 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 neuCA15-3 test is initially being developed as an improved monitoring test for breast cancer.

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 US$4.3b in 2022 and is expected to reach US$7.7b by 2030.[4] The intended use of the neuCA15-3 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.[5] 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 more accurate and cost-effective blood tests to improve breast cancer detection and monitoring. INOVIQ's neuCA15-3 test has the potential to deliver high sensitivity and specificity for detection and monitoring of breast cancer.

[1] neu5Gc = the sialic acid, N-glycolylneuraminic acid
[2] CA15.3 = Cancer Antigen 15.3 biomarker used as an aid for monitoring breast cancer treatment response
[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, 2023 – 2030. 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.