ASX Announcement

6 June 2023

BCAL Findings Presented at 2023 ASCO Annual Meeting

Highlights

- **Presentation at American Society of Clinical Oncology (ASCO) demonstrates potential to detect breast cancer using plasma lipidomic biomarker signature**
- **Results reduce the complexity and advance commercial viability of BCAL test**
- **BCAL laboratory now operational to advance clinical research, analytical and clinical validation studies**
- **Pathway for laboratory developed test (LDT) to be available to patients and medical community**

BCAL Diagnostics Limited (ASX:BDX) (BCAL or Company) today announced the presentation of data demonstrating the potential for detection of early breast cancer using a plasma lipidomic biomarker signature. BCAL is developing a non-invasive blood screening test that is intended to be used alongside breast cancer screening methods, such as mammography. The poster, "Lipidomic Signature From Plasma to Detect Localised Breast Cancer," was presented at the 2023 ASCO Annual Meeting (Chicago, 2 -6 June 2023).

"Our study demonstrated that the plasma lipid signature performance was highly accurate and comparable to the plasma-enriched extracellular vesicles (EV) cohort, a more time intensive and complex step," said Dr. Gillian Lamoury, Royal North Shore Hospital. "These findings strongly support the utility of the lipid signature in plasma to effectively distinguish people with localised breast cancer from healthy controls."

The use of plasma enables a method that is routine for blood sampling, which decreases the cost of delivery and increases patient access to the test.

"Breast cancer is the most common cancer among women and the second most common cause of death from cancer, but with early diagnosis and intervention, clinical outcomes can be improved, and lives saved," said Dr. John Hurrell, CEO, BCAL Diagnostics. "An effective and accurate blood test to detect localised breast cancer may increase the detection rate and improve patient outcomes. We are encouraged by the results of this study which was designed to reduce the complexity and advance the commercial viability of BCAL's novel blood test, BCAL Dx, for breast cancer detection."

About the Study

Following previous studies of lipid signatures derived from plasma-enriched extracellular vesicles that effectively distinguished people with localized breast cancer from cancer-free controls, BCAL aimed to investigate the utility of the lipid signature directly in plasma samples eliminating the EV enrichment step.

Lipids were extracted from enriched EVs from plasma samples donated by fasted people with localised breast cancer and control samples (n=793) and analysed by high resolution liquid chromatography-mass spectrometry (LC-MS). Over 400 manually curated lipids were quantified. Following variable selection, a lipid signature capable of distinguishing breast cancer samples from controls was derived. The lipid signature was modelled on each of the cohorts using leave-one-out internal cross-validation. Researchers then analysed the lipids in cancer and control (n=256) plasma samples corresponding to patients from Cohorts 3 and 4 previously used for EV preparations, and applied the signature derived using EVs on plasma lipidomic data.

EV samples of people with breast cancer were distinguished from controls with an area under the curve (AUC) of 0.77-0.89 across four cohorts. When the lipid signature was assessed directly from plasma the test achieved a comparable AUC of 0.84. Assessing the markers directly from plasma samples would make the test more scalable, higher throughput and easier to perform.

The study demonstrated the high performance of a lipid biomarker signature derived from plasma enriched EVs for early detection of localised breast cancer. The results suggest that the lipidomic signature could potentially be assessed directly from plasma samples instead of EVs reducing the test complexity. Ongoing studies will optimise the plasma lipidomic signature and prospectively compare the test against mammographic and pathological diagnoses.

Plasma Liquid Signature Performance is Comparable to EVs

Performance (LOOCV)	EV 256 Samples	Plasma 256 Samples
Accuracy	0.78	0.79
Sensitivity	0.81	0.79
Specificity	0.74	0.78
Pos Pred Value	0.82	0.84
Neg Pred Value	0.73	0.73
AUC	0.85	0.85

The Company continues to make significant clinical development progress and has conducted multiple studies of more than 1,200 patients. The test will initially complement current imaging technologies, such as the mammogram, particularly for women in the high-risk category due to breast tissue density or genetic predisposition.

BCAL recently announced the opening of its new development and clinical services laboratory that will utilize the newest Liquid Chromatography Mass Spectrometry (LCMS) platforms to continue to advance the findings of the Company's clinical research to-date and the progress made by BCAL Diagnostics' US development partner, Precion Inc. to establish and validate workflows and test protocols. This new laboratory will also serve as the testing site for the ongoing and planned analytical and clinical validation studies and will establish the quality systems and protocols to be compliant with ISO 15189, CLIA accreditation, NPAAC (National Pathology Accreditation Advisory Council) certifications and requirements of the *Therapeutic Goods Act 1989* (Cth).

The successful completion of these studies and receipt of the accreditations will allow the BCAL blood test to be available to the medical community and patients as an in-house developed test, also known as a laboratory-developed test or LDT. Patient samples will be collected and forwarded to BCAL's laboratory, where they will be tested for the proprietary BCAL lipid signature that is expressed by breast cancer cells.

To learn more about BCAL Diagnostics or to participate in BCAL's research, you can register your interest online at www.bcaldiagnostics.com.

This ASX announcement has been approved for release by the Board of BCAL.

About BCAL Diagnostics Limited (BCAL)

BCAL Diagnostics Limited is an Australian biotechnology company committed to improved health outcomes for women. Over the past decade, BCAL has developed a non-invasive blood screening technology that is initially intended to be used alongside breast cancer screening methods. The technology will initially complement current imaging technologies, such as the mammogram, while BCAL further progresses the development of a monitoring and screening test suitable for women of all ages and backgrounds in any location. With more than two million new cases of breast cancer diagnosed globally each year, a substantial opportunity exists for BCAL to improve patient outcomes. BCAL has partnered with Precion Inc. to optimize protocols and procedures for the clinical studies required for regulatory approvals across several jurisdictions, commercialization and market entry points. Founded in 2010, BCAL is headquartered in Sydney and listed on the Australian Securities Exchange (ASX:BDX).

For more information: https://www.bcaldiagnostics.com

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