

AUSTRALIAN CLINICAL STUDIES LAUNCHED WITH COLLECTION OF BLOOD SAMPLES

- **Sydney Breast Clinic is now collecting samples as part of the next stage of BCAL's breast cancer diagnostic development program**
- **Other clinical partners expected to join the study in the coming months**
- **Stage 1 of the diagnostic test development program will analyse blood from 1,000 participants, which will evaluate candidate biomarkers, optimise the algorithm for analysing biomarker differences between samples and establish improved workflows for the BCAL test**

Breast cancer screening and diagnostic company BCAL Diagnostics (ASX:BDX, 'BCAL' or the 'Company') is pleased to announce that it has commenced collecting samples for the first stage of its Australian clinical program, to be used for validation and performance evaluation of its blood-based test for detection of breast cancer.

In the first instance the test is being trialled for use as an adjunct to mammography, to help improve the accuracy of this commonly used diagnostic approach. This trial will confirm the set of candidate markers used in its breast cancer diagnostic test to distinguish between healthy women and those affected with breast cancer, as well as informing the design of the following pivotal clinical trial which will underpin regulatory approval.

BCAL's clinical partner Sydney Breast Clinic is now collecting blood samples from patients having mammograms at its Sydney CBD location.

NSW BreastScreen at Royal Prince Alfred Hospital (RPA) is currently closed due to COVID19, but will commence collection of samples once the clinic reopens under the guidance of Director Dr Wendy Vincent.

Other key Sydney-based investigational sites are planned to join the program over the coming months. These include Chris O'Brien Lifehouse under the guidance of A/Professor Sanjay Warriar, and A/Professor Cindy Mak. Collections are also expected to begin at a Melbourne site located adjacent to the Epworth Hospital next month. BCAL will make further announcements as these additional sites come online throughout the rest of the calendar year.

Stage 1 of the diagnostic test program will analyse blood from 1,000 participants. These samples will be used to validate and assess analytical performance of the candidate biomarkers, optimise the algorithm and establish protocols suitable for transfer of the test to commercial pathology laboratories.

These initial stages of product development will derive data that is required for subsequent regulatory approval and will inform the design and timing of BCAL's pivotal clinical trial. This trial will determine the clinical performance of the diagnostic test such that it will meet its initial intended purpose as an adjunct test to the mammogram in aiding a more accurate diagnosis of breast cancer.

Executive Chair Jayne Shaw commented: "Commencement of these studies marks a key milestone for BCAL as we further validate our test and continue toward commercialisation of a viable, accurate blood-based diagnostic for breast cancer diagnosis."

"We look forward to bringing results to the market and providing continued updates. BCAL is participating in several activities in conjunction with Breast Cancer Awareness Month during October, with details to become available on the company's website."

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

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About BCAL Diagnostics

BCAL Diagnostics Limited is an Australian screening and diagnostic company committed to the early, accurate diagnosis of breast cancer, and therefore early intervention and improved outcomes for women. Over the past decade BCAL has developed a non-invasive blood test for the detection of breast cancer, with results to date demonstrating 91% specificity and 87% accuracy. The test is initially designed to complement current imaging technologies, such as the mammogram, with the aim of becoming a monitoring and screening tool 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 global integrated cancer care and cardiac provider GenesisCare to conduct clinical research required for regulatory approvals across several jurisdictions, commercialisation 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/>