



ASX Announcement

29 November 2023

BCAL Diagnostics, the Krishna Institute of Medical Sciences (KIMS) and Indo-American Hospitals in Hyderabad, India initiate clinical studies using the BCAL breast cancer blood test in India

- BCAL Diagnostics and the KIMS and Indo-American Hospitals in Hyderabad have agreed to collaborate in a pilot study assessing the feasibility of using BCAL's blood-based lipidomic test for early diagnosis of breast cancer in India.
- There are significant survival rate disparities for women diagnosed with breast cancer in India compared to the USA and Australia.
- Emphasising the limitations of current screening methods in India, the BCAL blood test is positioned as a potential solution to overcome barriers, offering early detection and addressing challenges such as accessibility, skilled resources, radiation exposure, and cultural barriers.
- The collaborative study aims to evaluate sample collection and preparation workflows at the two Hyderabad hospitals, with processed samples being analysed in the BCAL laboratory in Sydney, Australia and potentially leading to a broader collaboration.

BCAL Diagnostics (ASX:BDX) (BCAL or Company) is pleased to announce that it has signed a Clinical Trials Research Agreement with Krishna Institute of Medical Sciences (KIMS) Hospital in Hyderabad, India. This will be a pilot study evaluating the feasibility of BCAL's blood-based lipidomic test for breast cancer at two sites in Hyderabad, the KIMS Hospital and Basavatarakam Indo-American Hospital in Hyderabad.

This collaborative study will evaluate feasibility of implementing the sample collection and preparation workflows at the hospitals. In the initial stage the processed samples will be tested in BCAL with results sent back to the investigators in India. If these clinical studies are successful, a broader collaborative relationship would provide Indian women with a more accessible and acceptable option for breast cancer screening.

The predicted 5-year survival rate for women in India diagnosed with breast cancer during 2010-2014 was 66.1%, in comparison to 90.2% in the USA and 89.5% in Australia. Late-stage diagnosis of breast cancer is one of the main reasons for poor prognosis of the disease. If breast cancer is diagnosed early, before any spread of the disease, the 5-year survival rate can be increased to as high as 99%.

Reasons for the late-stage diagnoses in India are primarily related to limitations of mammography, the current global breast cancer screening gold standard. Apart from the general problems with mammography, such as radiation exposure and its ineffectiveness in younger women, limitations particularly applying in India include:

- lack of accessibility for the screening, as only major and mid-sized Indian cities have screening facilities
- Lack of skilled human resources, since the number of available radiologists in India is 1 per 100,000 population, which is insignificant in comparison to the breast cancer burden
- Cultural barriers which are a concern in rural regions, since rural females are unwilling to test unless the condition is severe, or the cancer is in the advanced stage
- If available, mammography is expensive so many poorer rural women avoid this screening procedure, leading to an increase in cancer burden in rural regions

The BCAL blood test for breast cancer, BREASTEST™, could provide a solution to many of these barriers to early detection.

A/Prof Gillian Lamoury, Breast Cancer Specialist Radiation Oncologist, Royal North Shore Hospital/ University of Sydney Medical Advisor BCAL (India/ Middle East) commented *"The collaboration between these two large cancer hospitals in Hyderabad/India and BCAL Diagnostics marks a significant milestone in medical research. Together, we are embarking on a pioneering clinical study that aims to revolutionise early breast cancer detection in India using BCAL Diagnostics' innovative blood-based lipidomic test. The outcomes of these trials have the potential to transform breast cancer screening, offering a more accessible and widely embraced option for Indian women."*

Dr.Raghu Ram Pillarisetti OBE, Founding Director, KIMS-USHALAKSHMI Centre for Breast Diseases@KIMS Hospitals Padma Shri & Dr B.C. Roy awardee Officer of the Most Excellent Order of British Empire (OBE) commented *"KIMS-USHALAKSHMI Centre for Breast Diseases based out of KIMS Hospitals in Hyderabad (India) is thrilled to partner with BCAL Diagnostics in spearheading this groundbreaking clinical study. By leveraging the power of BCAL's innovative blood-based lipidomic test and integrating our unique insights, our shared objective is to overcome the barriers obstructing early breast cancer detection in India."*

Jayne Shaw, BCAL Chair commented *"This partnership with premier Indian medical institutions KIMS Hospitals and Basavartarakam Indo-American Hospitals, led by the eminent clinician Dr. Raghu Ram Pillarisetti OBE, marks a major advance for BCAL, as it strives to make its proprietary technology available to women globally and contribute to the improved survivability of breast cancer patients in India."*

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

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Jayne Shaw

Executive Chair

Jshaw@bcaldiagnostics.com

John Hurrell

Chief Executive Officer

jhurrell@bcaldiagnostics.com

Shane Ryan

Chief Operating Officer

sryan@bcaldiagnostics.com

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 90% specificity and 85% 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.

Founded in 2010, BCAL is headquartered in Sydney and listed on the Australian Securities Exchange (ASX:BDX). For more information: <https://www.bcaldiagnostics.com/>