

## EXCELLENT SUBB2M BREAST CANCER TEST DATA

- **Griffith University releases additional data on BARD1's SubB2M technology showing 100% specificity and over 95% sensitivity for detection of all stages of breast cancer**
- **BARD1 aims to develop and commercialise SubB2M-based blood tests for breast cancer to enable earlier detection, inform treatment decisions and improve women's health outcomes**

**Melbourne, Australia, 15 February 2021:** BARD1 Life Sciences Limited (ASX:BD1) (**BARD1** or the **Company**) is pleased to announce that Griffith University's Institute for Glycomics has now released data showing that SubB2M can be used to detect all stages of breast cancer with 100% specificity and over 95% sensitivity from a blood sample.

The presentation, entitled "*An engineered lectin, SubB2M, can detect N-glycolylneuraminic acid biomarkers in sera from breast cancer patients*", was delivered by Dr Lucy Shewell from Griffith University's Institute for Glycomics at the Lorne Cancer Conference.

Dr Shewell reported that serum from 96 patients with all stages of breast cancer had significantly elevated mean levels of Neu5Gc glycans compared to 22 cancer-free control individuals when assayed by surface plasmon resonance. The research also demonstrated the potential of SubB2M for the monitoring of patients for disease recurrence. Dr Shewell concluded that detection of Neu5Gc-glycans using SubB2M has the potential to be useful as a diagnostic marker for the detection of early-stage breast cancer, as well as a tool for monitoring disease progression in late-stage cancer.

This follows last week's announcement that the Griffith University group had reported similar results for SubB2M detection of Neu5Gc in ovarian cancer.

BARD1 CSO Dr Peter French said: "Whilst this data is preliminary, these excellent results reported by the researchers at Griffith University support the commercial potential of SubB2M for both breast and ovarian cancer monitoring and detection. This is ground-breaking research since Neu5Gc is a highly specific marker for cancer and BARD1 is using SubB2M alone or in combination with other tissue-specific cancer markers to develop highly-specific tests for breast, ovarian, prostate and pancreatic cancers."

Griffith University's Professor Mike Jennings said: "The SubB2M technology has proved to have remarkable sensitivity and specificity for detection of these aberrant sugar biomarkers in blood for both breast and ovarian cancers. There is potential to combine the detection of the Neu5Gc biomarkers by SubB2M with antibodies that recognise the cancer-specific biomarkers decorated with Neu5Gc. Work to develop a breast cancer-specific test using this dual detection approach is already underway, supported by the Biomedical Translation Bridge (BTB) grant from the federal government awarded to BARD1 to support work at Griffith University and the University of Adelaide."

BARD1 CEO Dr Leeane Hinch said: "Our SubB2M technology is a revolutionary platform with potential for the development of tests for monitoring and detection of multiple cancers. A non-invasive, accurate and reliable blood test for monitoring breast cancer has the potential to enable earlier detection, inform treatment decisions and improve health outcomes for women diagnosed with this deadly cancer."

BARD1 plans to develop and commercialise SubB2M-based blood tests initially for monitoring patients already diagnosed with breast cancer for treatment response and recurrence. BARD1 expects to report outcomes from its SubB2M ELISA test validation studies by end of 3Q CY2021.

In addition, it is expected that the SubB2M technology could be used to improve the specificity of existing commercial diagnostic tests, potentially enabling development and commercialisation of fast-to-market blood tests such as the PSA test for prostate cancer.

*Authorised by the Company Secretary, Tony Di Pietro.*

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## ABOUT BARD1 LIFE SCIENCES LTD

BARD1 Life Sciences Ltd (ASX:BD1) (**BARD1** or the **Company**) is a leading Australian diagnostics company with an innovative portfolio of diagnostic technologies and products. The Company is focused on developing and commercialising best-in-class diagnostic solutions for healthcare professionals and patients. The cancer diagnostics portfolio includes the commercialised hTERT test used as an adjunct to urine cytology testing and diagnostic tests in development for ovarian, breast, lung, prostate and pancreatic cancers. For more information on BARD1, see [www.bard1.com](http://www.bard1.com).

## ABOUT GRIFFITH UNIVERSITY'S INSTITUTE FOR GLYCOMICS

Griffith University's Institute for Glycomics is one of Australia's flagship multidisciplinary biomedical research institutes, comprising over 200 researchers, postgraduate students and support staff. The Institute for Glycomics strives to be a world leader in the discovery and development of novel drugs, vaccines and diagnostics through the application of innovative multidisciplinary science in a unique research environment. Their expertise centred around glycomics research makes them the only institute of its kind in Australia and one of only a handful in the world.

## ABOUT THE SUBB2M TECHNOLOGY

SubB2M is a novel protein that has been engineered to bind with high specificity and affinity to a glycan (Neu5Gc) that is only present on cancer cells and cancer-associated biomolecules. The SubB2M technology is a pan-cancer probe that is specific for cancer cells and has the potential to complement other technologies and biomarkers to detect cancer using a range of testing modalities, such as liquid biopsies, immunoassays, circulating tumour cell assays and positron emission tomography imaging.

## ABOUT BREAST CANCER

Breast cancer is the most common cancer and leading cause of cancer death in women worldwide, with an estimated 7.8 million survivors (5-year prevalence), 2.3 million new cases diagnosed, and 685,000 deaths in 2020<sup>1</sup>. Breast cancer is a potentially curable disease if diagnosed and treated appropriately at an early stage. SEER reports improved prognosis of breast cancer diagnosed at an early stage (Stage I/II) with 5-year survival of 86%-99% compared to late-stage detection (Stage III/IV) of 28%-86%<sup>2</sup>. Access to non-invasive, accurate and reliable blood tests for the detection and monitoring of breast cancer could greatly improve outcomes for women by providing earlier diagnosis, informed treatment and ongoing monitoring for recurrence.

## FORWARD LOOKING STATEMENTS

This announcement contains certain 'forward-looking statements' within the meaning of the securities laws of applicable jurisdictions. Forward-looking statements can generally be identified by the use of forward-looking words such as 'may,' 'should,' 'expect,' 'anticipate,' 'estimate,' 'scheduled' or 'continue' or the negative version of them or comparable terminology. Any forecasts or other forward-looking statements contained in this announcement are subject to known and unknown risks and uncertainties and may involve significant elements of subjective judgment and assumptions as to future events which may or may not be correct. There are usually differences between forecast and actual results because events and actual circumstances frequently do not occur as forecast and these differences may be material. The Company does not give any representation, assurance or guarantee that the occurrence of the events expressed or implied in any forward-looking statements in this announcement will actually occur and you are cautioned not to place undue reliance on forward-looking statements.

<sup>1</sup> Ferlay et al 2020. Global cancer statistics 2020: GLOBOCAN estimates of cancer incidence and mortality worldwide. IARC; 2020.

<sup>2</sup> SEER 2020. Cancer Stat Facts: Female Breast Cancer – Survival by Stage.

<https://seer.cancer.gov/statfacts/html/breast.html>