

## SUBB2M BREAST CANCER TEST MANUSCRIPT SUBMITTED

- **New manuscript submitted on BARD1's licensed SubB2M technology showing 100% specificity and over 95% sensitivity in differentiating all stages of breast cancer, including rare subtypes, from cancer free control sera**
- **The manuscript pre-print is available for viewing and downloading online**
- **BARD1 is developing and commercialising SubB2M-based blood tests for breast cancer to enable earlier detection, inform treatment decisions and improve women's health outcomes**

**Melbourne, Australia, 25 June 2021:** BARD1 Life Sciences Limited (ASX:BD1) (**BARD1** or the **Company**) is pleased to announce that researchers from Griffith University's Institute for Glycomics and the University of Adelaide have now submitted a manuscript to an international peer reviewed journal that discloses the full data, methods and results underlying the previously announced (15 February 2021) poster presentation showing that SubB2M can be used to detect all stages of breast cancer from blood samples with 100% specificity and over 95% sensitivity over healthy controls.

The pre-print manuscript, entitled "*N-glycolylneuraminic acid serum biomarker levels are elevated in breast cancer patients at all stages of disease*", is available to be downloaded on line at <https://biorxiv.org/cgi/content/short/2021.06.21.449179v1>.

The manuscript describes further important details on the SubB2M-based surface plasmon resonance (SPR) assay for breast cancer detection, including that the SPR-assay was able to detect common (invasive ductal carcinoma and invasive lobular carcinoma) as well as rare forms (mucinous carcinoma) of breast cancer, supporting its utility across multiple breast cancer subtypes and the potential widespread commercial viability. This independent SubB2M study was supported by a grant from the US Department of Defense (W81XWH-20-1-0527).

BARD1 was recently awarded funding from MTPConnect's Biomedical Translation Bridge (BTB) program to develop SubB2M-based tests for breast cancer detection and monitoring. The BTB program is provided by the Australian Government's Medical Research Future Fund, with support from the Medical Device Partnering Program.

BARD1 CSO Dr Peter French said: "Once published, we expect that this manuscript will add to the mounting data supporting the use of SubB2M as a novel probe for detection of a range of cancers. SubB2M binds to the sugar Neu5Gc which is known to be a highly specific marker for cancer. BARD1 is working with Griffith University's Institute for Glycomics and the University of Adelaide to develop SubB2M alone and in combination with other tissue-specific cancer markers as highly-specific tests for breast and ovarian cancers."

Griffith University's Professor Mike Jennings said: "The SubB2M technology has proved to have exquisite sensitivity and specificity for detection of cancer-associated sugar in serum of both breast and ovarian cancers. We are now working with BARD1 to develop first-in-class SubB2M-based enzyme-linked immunosorbent assays (ELISAs) that are specific for breast and ovarian cancers, with potential commercial uses for both monitoring and early detection."

BARD1 CEO Dr Leearne Hinch said: "A SubB2M-based blood test for breast cancer has the potential to enable earlier detection, inform treatment decisions and improve health outcomes for women diagnosed with this deadly cancer. It is very pleasing that this exceptional breast cancer data has now been submitted for peer review."

The SubB2M technology is a potential game-changer for developing highly specific blood tests for detection of multiple cancers. BARD1 initially plans to develop and commercialise SubB2M-based blood tests for monitoring treatment response and recurrence in patients already diagnosed with breast cancer. The Company then plans to undertake further studies to expand indications for use as a screening test for early detection of breast cancer in asymptomatic women.

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

- ENDS -

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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. BARD1 has commercialised the hTERT test used as an adjunct to urine cytology testing for bladder cancer and the EXO-NET pan-exosome capture tool for research purposes. Our cancer diagnostic pipeline includes tests in development for ovarian and breast cancers, and research-stage projects for 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 sugar called Neu5Gc that is present in human cancers including cancer cells, cancer-associated biomolecules and secretions. The SubB2M technology has the potential to improve the specificity of other cancer biomarkers and complement other cancer diagnostic technologies including immunoassays, circulating tumour cell assays and positron emission tomography imaging. BARD1 has the exclusive worldwide license to the SubB2M technology from the University of Adelaide for use in diagnostic applications.

## 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 minimally-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.

## BIOMEDICAL TRANSLATION BRIDGE PROGRAM

The Biomedical Translation Bridge Program delivered by MTPConnect is a \$22.3 million Medical Research Future Fund initiative that provides up to \$1 million in matched funding to nurture the translation of new therapies, technologies and medical devices through to proof of concept to turn innovative medical ideas into reality.

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<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>

## 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.