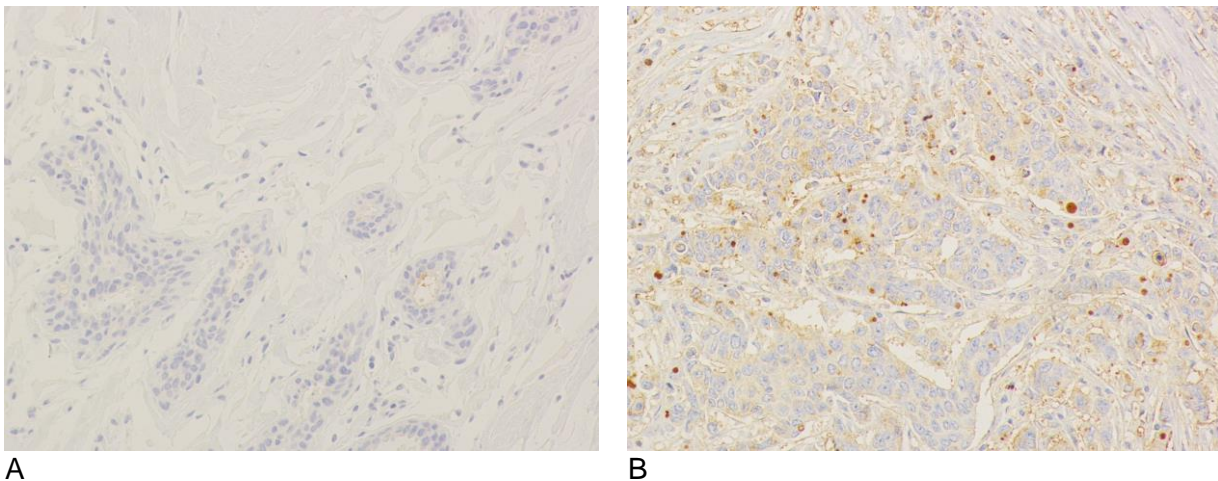


## BARD1 DEMONSTRATES FEASIBILITY OF SUBB2M-BASED IHC TEST

- New preliminary study demonstrates the feasibility of using BARD1's novel pan-cancer probe, SubB2M, in immunohistochemistry (IHC) on breast cancer tissue
- Further optimisation is needed to determine optimal binding conditions and clinical utility across a range of cancers
- SubB2M-based IHC applications represent a potential fast-to-market product opportunity for BARD1's expanding cancer diagnostic pipeline

**Melbourne, Australia, 25 May 2021:** BARD1 Life Sciences Limited (ASX:BD1) (**BARD1** or the **Company**) is pleased to announce the results of a preliminary study which demonstrates the feasibility of using SubB2M in an IHC application for breast cancer tissue. SubB2M is a protein that binds specifically to a sugar, Neu5Gc, that is associated with a range of cancers.

This is the first time that SubB2M has been used to visualise staining of cancer in formalin-fixed, paraffin-embedded (FFPE) tissue sections. The study compared cancer tissue from an invasive ductal breast cancer tumour biopsy to a non-cancer breast tissue biopsy. Figure 1 depicts images from the initial experiment showing that a SubB2M-based IHC had a differential staining pattern in invasive breast cancer (B: brown stained tissue) compared to non-cancer tissue (A: unstained).



*Figure 1: SubB2M-based IHC in FFPE breast cancer and control tissue sections. A. Normal (non-cancer) breast tissue stained with SubB2M. Lack of brown staining indicates no binding of SubB2M. B. SubB2M binding was seen throughout the breast cancer tissue, as indicated by brown staining.*

This preliminary study also demonstrated that the SubB2M IHC test could be performed on automated staining instrumentation used in pathology laboratories worldwide. Once the staining has been optimised for breast cancer tissue, BARD1 plans to extend its SubB2M-based IHC studies to other cancer applications.

BARD1 CSO, Dr Peter French, said: "Whilst this data is from a single patient sample, and the assay conditions have not been optimised, we are pleased that we were able to utilise SubB2M to achieve a positive staining outcome in breast cancer FFPE sections. This is the first time SubB2M has been used in a histopathology application, and it demonstrated both initial feasibility in an IHC application for breast cancer and compatibility with an automated staining instrument."

Dr Learne Hinch, BARD1 CEO, said: "This initial feasibility data indicates that our SubB2M technology may be expanded to IHC applications for tissue-based cancer diagnosis. This represents a potential fast-to-market product opportunity for BARD1's expanding cancer diagnostic pipeline. The global immunohistochemical market was valued at US\$1.8 billion in 2019<sup>1</sup> and SubB2M-based IHCs could be developed for cancers such as melanoma where it can be difficult to distinguish malignant from benign tissues."

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

- ENDS -

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## ABOUT BARD1 LIFE SCIENCES LTD

BARD1 Life Sciences Ltd (ASX:BD1) 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 based on its BARD1, SubB2M, and Molecular NETs platforms for healthcare professionals and patients. The cancer diagnostics portfolio includes the commercialised hTERT test used as an adjunct to urine cytology and development-stage tests for ovarian, breast, prostate and pancreatic cancers. The Company is also commercialising its Molecular NETs platform for sample preparation and has launched its first proprietary EXO-NET<sup>®</sup> exosome capture tool for use in research for exosome-based diagnostics and therapeutics. For more information on BARD1 and EXO-NET, visit [www.bard1.com](http://www.bard1.com) and [www.exo-net.com](http://www.exo-net.com).

## ABOUT SUBB2M, NEU5GC AND IHC

SubB2M is a protein that binds specifically to a sugar, Neu5Gc, that is associated with a range of cancers. Normal human cells and tissues do not typically express Neu5Gc. Incorporation of Neu5Gc in cancer cells is most prominent in soluble glycoproteins found both in the extracellular space and inside the cell, and Neu5Gc is the dominant sugar in glycoproteins secreted from cancer cells into the surrounding tissues<sup>2</sup>. Researchers from the University of Adelaide and Griffith University's Institute for Glycomics have engineered the SubB2M protein to have exquisite specificity for binding to Neu5Gc, and have reported its ability to detect Neu5Gc in the bloodstream of breast and ovarian cancer patients.

IHC in routine histopathology currently utilises antibodies for the detection of antigens in tissue sections that are normally over- or under-expressed in cancer tissue compared to normal tissue to assist in the diagnosis of cancers. IHC plays an essential role in pathology, particularly in the sub-specialties of oncologic pathology, neuropathology, and hematopathology.

## 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> <https://www.grandviewresearch.com/industry-analysis/immunohistochemistry-ihc-market>

<sup>2</sup> Day et al, 2017. Structure aided design of a Neu5Gc specific lectin. *Scientific Reports* 7: 1495 | DOI:10.1038/s41598-017-01522-9