BARD1 AWARDED BIOMEDICAL TRANSLATION BRIDGE FUNDING TO DEVELOP BREAST CANCER TESTS

- **BARD1 to develop first-in-class SubB2M-based liquid biopsy tests to detect and monitor breast cancer treatment response and recurrence**
- **Awarded $372,654 in matched funding from competitive Biomedical Translation Bridge (BTB) program**
- **Project aims to develop, validate and commercialise non-invasive, accurate and reliable blood tests for breast cancer to enable earlier detection, inform treatment decisions and improve women's health outcomes**

Melbourne, Australia, 3 September 2020: Medical diagnostics company BARD1 Life Sciences Limited (ASX:BD1) (**BARD1** or the **Company**) is pleased to announce the award of $372,654 in grant funding from the Biomedical Translation Bridge (**BTB**) program to develop, clinically evaluate and commercialise liquid biopsy tests to detect and monitor breast cancer using its proprietary SubB2M cancer-specific probe.

Delivered by MTPConnect, the Australian Government's BTB program is a $22.3 million Medical Research Future Fund (**MRFF**) 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, turning innovative medical ideas into reality.

Successful B2B program Round 2 applicants were announced today by the Minister for Health the Hon Greg Hunt MP. The SubB2M program was awarded Federal Government funding after being assessed by an independent Investment Panel. BARD1 must provide matched funding and enter a funding agreement with MTPConnect.

BARD1 CEO, Dr Leearne Hinch, said: "We greatly appreciate the support of the competitive BTB program and believe this reflects the importance and commercial potential of our novel SubB2M liquid biopsy project to detect and monitor breast cancer treatment response and recurrence. The SubB2M molecule binds to a cancer-specific sugar molecule that is only found on human cancer cells, potentially enabling the development of highly-specific blood tests with low false positives. We believe that our SubB2M-based liquid biopsy tests could radically improve how breast cancer is detected and monitored, addressing this important unmet need in women's health."

The BTB funding will allow the Company to build on previous data generated from researchers at the University of Adelaide and Griffith University to advance development of a simple. non-invasive breast cancer test to detect and monitor breast cancer. In pilot clinical studies using patient serum samples assayed by surface plasmon resonance (**SPR**), SubB2M detected cancers with 100% sensitivity and specificity for mid to late-stage cancers, and >95% specificity and 100% sensitivity for early-stage cancers. There is also evidence that the cancer-specific sugar detected by SubB2M is present in a wide range of other solid human tumours and can be detected in serum using SubB2M.

Breast cancer is the most common cause of cancer-related mortality among women, with an estimated 2.8 million new cases and 626,679 deaths worldwide in 2018[1]. 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. With the support of the BTB program, BARD1 plans to develop and commercialise SubB2M-based liquid biopsy tests for monitoring patients already diagnosed with breast cancer for treatment response and recurrence, and as an adjunct to screening mammography.

The project work will be performed collaboratively by BARD1, the Institute for Glycomics at Griffith University and the Paton Laboratory at the University of Adelaide over 22 months. A key objective of the project is to develop a SubB2M enzyme-linked immunosorbent assay (**ELISA**) assay for monitoring of

[1] World Health Organisation (WHO), 2020

treatment response and recurrence in breast cancer patients. Key milestones include validation of a SubB2M ELISA format test expected by end-2021 and potential launch of a SubB2M laboratory developed test (**LDT**) in the USA for treatment monitoring of breast cancer by mid-2022.

BARD1 Chief Scientific Officer, Dr Peter French, said: "SubB2M is potentially one of the most exciting breakthroughs in cancer diagnostics that I have seen in 40 years of medical research. The primary objective of the BTB funded program is to develop two SubB2M-based liquid biopsy tests for adjunctive screening and monitoring in an ELISA format, a platform that is widely available in routine pathology laboratories. Each assay will be characterised for accuracy using clinical serum samples from breast cancer patients, and disease-free women, with the goal of demonstrating scientific, clinical, and commercial proof-of-concept of the tests before commercial launch."

Importantly, a validated SubB2M ELISA assay will enable the Company to evaluate a range of proprietary new SubB2M-based tests using SubB2M alone or in combination with other cancer biomarkers (including BARD1 autoantibody tests) to develop highly-specific tests for screening and monitoring of various cancers. BARD1 intends to expand applications for the SubB2M ELISA assay to improve the specificity of existing commercial diagnostic tests, potentially enabling development and commercialisation of fast-to-market, next-generation blood tests for breast, ovarian and prostate cancers.

BARD1's cancer diagnostic portfolio also includes the revenue-generating hTERT test used as an adjunct to urine cytology testing and diagnostic tests in preclinical development for ovarian, breast, lung and pancreatic cancers. The Company has previously announced that it intends to grow its hTERT revenues globally, continue development of its BARD1 autoantibody program for screening high-risk individuals for ovarian, breast and lung cancers, and progress its EXO-NET research-use-only application and pancreatic cancer clinical application.

The Company aims to develop best-in-class diagnostic tests for healthcare professionals and patients using its platform technologies for the screening, diagnosis, prognosis, treatment selection and/or monitoring of cancers with significant unmet needs.

BARD1 had a post-Sienna acquisition cash position of approximately $10.4 million at 31 July 2020 that will be used to fund its ongoing research, development and commercial programs.

Authorised for release by Company Secretary, Tony Di Pietro.

- ENDS -

COMPANY CONTACTS

Dr Leearne Hinch
CEO
E leearne@bard1.com
M +61 400 414 416

Dr Geoff Cumming
Non-Executive Chairman
E geoff.cumming@bard1.com
M +61 417 203 021

ABOUT BARD1 LIFE SCIENCES LTD

BARD1 Life Sciences Ltd (ASX:BD1) (**BARD1** or the **Company**) is a leading Australian-based medical diagnostics company with an innovative portfolio of diagnostic technologies and products. The Company is focused on developing and commercialising best-in-class diagnostic tests for healthcare professionals and patients. The cancer diagnostics portfolio includes the marketed 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.

ABOUT THE BIOMEDICAL TRANSLATION BRIDGE (BTB) PROGRAM

The Biomedical Translation Bridge program is an initiative of the Australian Government's Medical Research Future Fund. The BTB program can provide up to A$1 million of funding over a maximum 22-month period to help eligible organisations fund and nurture early stage health and medical research to reach proof-of-concept with potential to attract further capital and support. The BTB program is operated by MTPConnect, in partnership with BioCurate (University of Melbourne and Monash University), UniQuest (University of Queensland through its drug discovery initiative QEDDI), the Medical Device Partnering Program (MDPP, led by Flinders University), and the Bridge and BridgeTech programs (Queenland

University of Technology); all pre-eminent organisations engaged in the translation and commercialisation of health and medical research.

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 associated secreted 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 tumor cell assays and positron emission tomography imaging.

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.