PROOF-OF-CONCEPT ACHIEVED FOR SUBB2M ELISA-BASED OVARIAN CANCER TEST

- **POC[1] achieved in feasibility studies demonstrating that a SubB2M[2]/CA125[3] ELISA[4] can detect the CA125 biomarker for ovarian cancer in patient samples**
- **SubB2M/CA125 ELISA-based test detects CA125-Neu5Gc[5], making it highly specific for CA125 from ovarian cancer**
- **Achievement of this key POC milestone supports and de-risks advancing the development of SubB2M ELISA tests for ovarian, breast, prostate and other cancers**

Melbourne, Australia, 17 August 2021: BARD1 Life Sciences Limited (ASX:BD1) (**BARD1** or the **Company**) is pleased to announce that proof-of-concept (POC) has been achieved for its SubB2M/CA125 enzyme-linked immunosorbent assay (ELISA)-based test for ovarian cancer. BARD1's collaborator, the Institute for Glycomics at Griffith University (Griffith), has demonstrated that an initial SubB2M/CA125 assay can detect CA125-Neu5Gc in serum from stages I-IV ovarian cancer (OC) patients compared to healthy controls at biologically relevant levels.

Previous research by the Griffith research team led by Professor Mike Jennings showed that a SubB2M surface plasmon resonance (SPR)[6]-based assay that measures binding of SubB2M to the cancer biomarker Neu5Gc, could detect elevated Neu5Gc at all-stages of OC with 100% sensitivity and specificity compared to healthy controls.[7] BARD1 initiated a development program in December 2020 to transfer the cancer biomarker SPR-assay to cancer-specific ELISA-based tests that combined tissue-specific cancer biomarkers such CA125 for OC, CA15-3 for breast cancer and PSA for prostate cancer. ELISA is a common and low-cost assay format that can be performed in commercial laboratories worldwide, including on high-throughput laboratory instrumentation. Development of a SubB2M/CA125 ELISA-based test has the potential to create an accurate, reliable, and affordable test for monitoring and early detection of OC.

Professor Mike Jennings of Griffith said: "We are pleased to have generated preliminary data that demonstrates POC for the SubB2M/CA125 test in an ELISA format showing that Neu5Gc-bearing CA125 could be detected in stages I-IV ovarian cancer serum samples and not healthy controls. We have successfully achieved initial assay design and feasibility testing and will now advance to the optimisation phase for the SubB2M/CA125 test."

Dr Peter French, BARD1 Chief Scientific Officer said, "These preliminary data are very encouraging for development of a robust and reliable SubB2M/CA125 test for monitoring and early detection of ovarian cancer. The feasibility studies at Griffith have demonstrated that the SubB2M assay can be transferred from a research-use SPR platform to a commercial platform with initial design of an ELISA including key reagents and assay conditions established in both spiked-in and now patient samples. Importantly, this initial assay development work is transferrable to our other SubB2M development programs including CA15-3 for breast cancer, PSA for prostate cancer and other cancers. These data represent a key go-decision to progress the optimisation and validation of our SubB2M ELISA-based tests that are expected to improve existing cancer biomarker tests for ovarian, breast, prostate and other cancers."

The next steps for the SubB2M OC program are to complete the optimization phase with testing of OC samples and healthy controls compared to SPR, followed by clinical testing to demonstrate the sensitivity and specificity of the SubB2M/CA125 test for detection of ovarian cancer across all stages compared to CA125 alone in archived samples from the Victorian Cancer Biobank. Further details on our SubB2M development plans and study designs will be provided in due course.

Authorised by the 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 diagnostics company with an innovative portfolio of diagnostic technologies and products. The Company is focused on developing and commercialising 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 and www.exo-net.com.

ABOUT THE SUBB2M/CA125 TEST

The SubB2M/CA125 test is being developed as a simple, fast and inexpensive ELISA-based blood test that detects CA125-Neu5Gc for the monitoring and early detection of ovarian cancer. The proprietary SubB2M protein binds to CA125-Neu5Gc from cancer cells, so the SubB2M/CA125 test is expected to have higher specificity for cancer derived CA125 (i.e. with Neu5Gc). CA125 can be elevated in serum due to conditions other than cancer, including endometriosis, pelvic inflammatory disease and pregnancy. BARD1 believes that a SubB2M/CA125 assay should significantly improve performance over existing CA125 tests with less false-positives, missed-diagnosis and over-diagnosis, positioning the SubB2M/CA125 test as the preferred test by clinicians, payors and patients for detection and monitoring of ovarian cancer.

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.

---

[1] POC = Proof of Concept
[2] SubB2M = engineered lectin (protein) that is a mutant of the B subunit of the subtilase cytotoxin that binds to Neu5Gc
[3] CA125 = cancer antigen 125. CA125 is a protein highly expressed in ovarian cancer cells and to lower levels in other tissues.
[4] ELISA = Enzyme Linked Immunosorbent Assay
[5] Neu5Gc = N-glycolylneuraminic acid
[6] SPR = Surface Plasmon Resonance
[7] Shewell et al. N-glycolylneuraminic acid serum biomarker levels are elevated in breast cancer patients at all stages of disease. Available: https://www.biorxiv.org/content/10.1101/2021.06.21.449179v2.full