POSITIVE RESULTS FROM THE BARD1 AUTOANTIBODY ASSAY

- **Independent study by Griffith University to evaluate the BARD1 kit for detection of ovarian cancer showed similar performance to previous results reported by UNIGE**
- **Both studies were performed using the multiplex BARD1 kit developed for use on the Luminex platform**
- **Data from both studies identified 3 consistent BARD1 peptides that were best able to discriminate ovarian cancer from controls**
- **CA125 in combination with 2 BARD1 peptides substantially improved sensitivity for detection of ovarian cancer over CA125 alone from 27% to 91%**

Melbourne, Australia, 29 April 2021: BARD1 Life Sciences Limited (ASX:BD1) (**BARD1** or the **Company**) is pleased to announce positive results from an independent study to evaluate the BARD1 autoantibody assay for detection of ovarian cancer using the BARD1 kit on the Luminex platform.

The BARD1 autoantibody assay is designed to measure the level of autoimmune antibodies to cancer-associated BARD1 isoforms. The BARD1 kit contains 20 peptides (short strings of amino acids) that represent potential epitopes (immunogenic regions) on the full length BARD1 protein and cancer-associated BARD1 isoforms (variant proteins).

Griffith University's Mucosal Immunology Research Group (MIRG) was contracted to evaluate the research use only (RUO) BARD1 kit alone and in combination with CA125 for detection of ovarian cancer in 241 samples, comprising 160 ovarian cancer patient samples and 81 healthy control samples.

The Company previously announced that a study to evaluate the RUO BARD1 kit for ovarian cancer undertaken at the University of Geneva (UNIGE) indicated that the number of peptides could be reduced whilst maintaining high levels of discrimination between ovarian cancer patients and controls. The significance of that result was that reducing the number of peptides would simplify the development and use of the test in a clinical setting.

This Griffith study aimed to evaluate the performance of the RUO BARD1 kit and compare with the previous results from UNIGE. Pleasingly, the Griffith University study also identified that a smaller subset of peptides could be used to discriminate ovarian cancer from controls, although several peptides differed between the two studies. When the data from both studies was combined and analysed by independent professional biostatistician Professor Val Gebski from Data Analysis and Research Technologies, three peptides provided consistent discrimination between cancer and controls. These same peptides were also identified in the first study conducted by UNIGE as discriminators of ovarian cancer.

Cancer antigen 125 (CA125) is a protein highly expressed in ovarian cancer cells that has been shown to have less than 50% sensitivity for detection of early-stage ovarian cancer. The CA125 test is the gold-standard FDA 510(k) cleared test for monitoring patients diagnosed with ovarian cancer.

When CA125 was included in the analysis of the combined dataset, the number of peptides required to discriminate cancer reduced further. Using just two peptides in combination with CA125 levels less than 70 Units/ml provided a sensitivity of 91% and a specificity of 50% for ovarian cancer in these samples. This sensitivity level was a substantial improvement over that obtained with CA125 alone (27%) in this group. The high level of sensitivity obtained by combining the BARD1 peptides with CA125 is encouraging for the potential use of this assay for early detection of ovarian cancer in high-risk women with Hereditary Breast and Ovarian Cancer syndrome (HBOC), given the importance of high sensitivity in this indication (Fawunmi et al, 2013).[1]

Further research, assay optimisation and technical validation of the BARD1 autoantibody test will be required to determine the robustness of the smaller peptide panel and CA125 combination before advancing towards clinical validation studies.

[1] David Fawunmi, Helene Gojon, and Antonis Valachis. The effectiveness of ovarian cancer screening in high-risk population and BRCA 1/2 carriers: A systematic review and meta-analysis. Journal of Clinical Oncology 2013 31:15_suppl, 1568-1568

BARD1 CSO, Dr Peter French, said: “The next step in the development of a reliable BARD1 autoantibody assay for ovarian cancer is to validate the selected peptides and CA125 in the algorithm identified by this combined data set in a larger independent data set to establish the sensitivity and specificity of the test. For a BARD1 ovarian cancer assay to be successfully commercialised, accurate and reliable assay performance must be established in independent laboratory settings across a broader patient population.”

BARD1 CEO, Dr Leearne Hinch, said: “These results are promising for the BARD1 autoantibody assay. We are committed to developing a test using our platform technologies to detect ovarian cancer early, save women’s lives and avoid unnecessary surgery in high-risk women with HBOC[2].”

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 based on its BARD1, SubB2M, Molecular NETs and hTERT platforms for healthcare professionals and patients. The cancer diagnostics portfolio includes the commercialised hTERT test used as an adjunct to urine cytology testing and development-stage tests for ovarian, breast, lung, prostate and pancreatic cancers. The Company is also commercialising its Molecular NETs platform for sample preparation and is launching its proprietary EXO-NET™ exosome capture tool for use in research for exosome-based diagnostics and therapeutics. For more information on BARD1 see www.bard1.com.

ABOUT THE BARD1-OVARIAN TEST

BARD1-Ovarian is a bead-based blood test in development for early detection of ovarian cancer in high-risk women. The test measures multiple BARD1 autoantibodies in the blood and uses a proprietary diagnostic algorithm to combine these levels into a cancer score that identifies the presence or absence of ovarian cancer. BARD1-Ovarian could potentially be used as a screening test for early detection of ovarian cancer in high-risk asymptomatic individuals, for risk assessment of malignancy in women with pelvic masses, or to monitor ovarian cancer recurrence.

ABOUT THE CA125 TEST

CA125 (cancer antigen 125) is a protein highly expressed in ovarian cancer cells and to lower levels in other tissues. The CA125 test is a commercially available test that measures the amount of CA125 in the blood. The CA125 test is clinically used as an aid in the diagnosis and management of ovarian cancer. CA125 levels greater than 35 U/mL usually indicate that ovarian cancer may be present. CA125 levels reflect tumour burden and are often higher in late-stage ovarian cancer, but can also be high in benign conditions, with numerous studies showing that the CA125 biomarker alone has limited sensitivity for detection of early-stage cancers and inadequate specificity for malignancy.

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

[2] Hereditary Breast and Ovarian Cancer syndrome

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.