BARD1 AUTOANTIBODY TEST RESULTS FOR OVARIAN CANCER PUBLISHED

- **Studies performed at the University of Geneva in 2018 for the Company's BARD1 autoantibody (AAb) test for detection of ovarian cancer published in international peer-reviewed journal Genes**
- **The research-stage BARD1 AAb assay showed a predicted accuracy of 0.96 with 86% sensitivity at 95% specificity cut-off for detection of ovarian cancer in asymptomatic women compared to healthy controls**
- **Similar high predicted accuracy of 0.97 for ovarian cancer was shown in high-risk women with hereditary breast and ovarian cancer syndrome (HBOC)**
- **The AAb-based test is one of the approaches that BARD1 is developing for ovarian cancer to enable earlier detection, save women's lives and avoid unnecessary surgery**

Melbourne, Australia, 29 June 2021: BARD1 Life Sciences Limited (ASX:BD1) (**BARD1** or the **Company**) today announced that previously reported study results for a potential BARD1 autoantibody test for early detection of ovarian cancer were published on the 25 June 2021 in the international peer-reviewed journal Genes.

The full-text article in Genes titled "BARD1 Autoantibody Blood Test for Early Detection of Ovarian Cancer" is available at https://doi.org/10.3390/genes12070969. The Abstract is provided below.[1]

Background: Ovarian cancer (OC) is the most lethal gynaecological cancer. It is often diagnosed at an advanced stage with poor chances for successful treatment. An accurate blood test for the early detection of OC could reduce the mortality of this disease.

Methods: Autoantibody reactivity to 20 epitopes of BARD1 and concentration of cancer antigen 125 (CA125) were assessed in 480 serum samples of OC patients and healthy controls. Autoantibody reactivity and CA125 were also tested for 261 plasma samples of OC with or without mutations in BRCA1/2, BARD1, or other predisposing genes, and healthy controls. Lasso statistic regression was applied to measurements to develop an algorithm for discrimination between OC and controls.

Findings and interpretation: Measurement of autoantibody binding to a number of BARD1 epitopes combined with CA125 could distinguish OC from healthy controls with high accuracy. This BARD1-CA125 test was more accurate than measurements of BARD1 autoantibody or CA125 alone for all OC stages and menopausal status. A BARD1-CA125-based test is expected to work equally well for average-risk women and high-risk women with hereditary breast and ovarian cancer syndrome (HBOC). Although these results are promising, further data on well-characterised clinical samples shall be used to confirm the potential of the BARD1-CA125 test for ovarian cancer screening.

The study data published in Genes were previously announced by the Company as positive results from its OC-CA125 and OC-R001 studies in ovarian cancer (announced on 19 June 2018 and 6 September 2018 respectively). These studies were performed at the University of Geneva (UNIGE) under a Research Agreement.

The Company is exploring several approaches for developing an accurate and reliable blood test for earlier detection of ovarian cancer utilising its proprietary BARD1 autoantibody (AAb) and SubB2M technologies. The BARD1 autoantibody approach in the above studies used a research-stage ELISA[2] performed on a research use only MSD[3] platform to detect autoantibodies to BARD1 variant proteins. Whilst this has shown promising data, the Company believes it requires considerable further assay development and technical validation on a commercial assay platform before advancement towards clinical development of a potential commercial test.

[1] Pilyugin M, Ratasjka M, Stukan M, Concin N, Zeillinger R, Irminger-Finger I. BARD1 Autoantibody Blood Test for Early Detection of Ovarian Cancer. *Genes*. 2021; 12(7): 969. https://doi.org/10.3390/genes12070969
[2] ELISA = Enzyme-linked immunosorbent assay
[3] MSD = Meso Scale Discovery

The Company is also developing a SubB2M-based approach that detects a pan-cancer marker called Neu5Gc. Proof of concept results using a research-stage SPR[4] assay showed outstanding accuracy for detection of ovarian cancer with 100% sensitivity and specificity across all stages compared to healthy controls. SubB2M-based ELISA blood tests are currently being developed for monitoring treatment response and recurrence in women previously diagnosed with ovarian cancer. The Company also plans to undertake further studies to expand indications for use of a SubB2M-based ELISA to a screening test for early detection of ovarian cancer in asymptomatic women. ELISA is a widely used commercial platform in pathology laboratories worldwide.

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 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.

ABOUT THE BARD1 OVARIAN CANCER TEST

BARD1-Ovarian is a blood test in development for early detection of ovarian cancer in high-risk women. The test measures multiple BARD1 autoantibodies and CA125 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 women with HBOC, or for risk assessment of malignancy in women with pelvic masses.

ABOUT OVARIAN CANCER

Ovarian cancer is the leading cause of gynaecological cancer deaths and eight most common cancer in women worldwide, with an estimated 823,00 survivors (5-year prevalence), around 314,000 new cases diagnosed and 207,000 deaths in 2020.[5] Ovarian cancer is often diagnosed at a late stage after symptoms have appeared, resulting in a poor prognosis with an overall 5-year survival rate of 49% in the US, and recurrence of around 70% after 12-18 months. Earlier detection by finding ovarian cancer when local rather than distant may increase 5-year survival from 30% to 93%, a potential survival improvement of 3 times.[6] There is a clear unmet clinical need for non-invasive, accurate and affordable diagnostic tests for the early detection and monitoring of ovarian cancer. The global ovarian cancer diagnostics market is estimated to be worth US$1.8B by 2026.[7]

[4] SPR = Surface Plasmon Resonance
[5] Ferlay et al 2020. Global cancer statistics 2020: GLOBOCAN estimates of cancer incidence and mortality worldwide. IARC; 2020.
[6] SEER 2020. Cancer Stat Facts: Ovarian Cancer – Survival by Stage. https://seer.cancer.gov/statfacts/html/ovary.html
[7] Acumen Research and Consulting. Ovarian Cancer Diagnostics Market Size Worth US$ 1.8 Bn by 2026. https://www.globenewswire.com/news-release/2019/08/07/1898453/0/en/Ovarian-Cancer-Diagnostics-Market-Size-Worth-US-1-8-Bn-by-2026.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.