SUCCESSFUL OPTIMISATION OF BARD1 KIT FOR OVARIAN CANCER

- **Ovarian cancer study confirms the optimised RUO BARD1 kit developed on the Luminex platform is suitable for detection of ovarian cancer**
- **Results showed good discrimination between cancer patients and controls with fewer peptides, potentially improving the ease of clinical use**
- **Next step is to independently validate the test at Griffith University**

Melbourne, Australia, 23 September 2020: Medical diagnostics company BARD1 Life Sciences Limited (ASX:BD1) (**BARD1** or the **Company**) is pleased to announce the successful evaluation of the BARD1 kit in ovarian cancer samples on the Luminex platform.

The primary aim of this ovarian cancer study (OC-L002), performed at the University of Geneva, was to evaluate the version 2 (v2) Research Use Only (RUO) BARD1 kit for detection of ovarian cancer.

The results showed a very strong correlation between the peptide signals from the optimised RUO BARD1 kit developed on the Luminex platform compared with previous data on the Meso Scale Diagnostics (MSD) platform using the same samples.

Further analysis of the data indicated that the number of peptides could be reduced while maintaining high levels of discrimination between ovarian cancer patients and controls. The significance of this result is that reducing the number of peptides simplifies the development and use of the test and algorithm in a clinical setting.

Luminex is an industry standard diagnostic platform used in clinical laboratories worldwide, potentially reducing development hurdles and enabling broader commercial access to the commercial BARD1 tests. The RUO BARD1 kit was developed by Thermo Fisher Scientific under a contract development agreement.

BARD1 CEO, Dr Leearne Hinch, said: “This is an important milestone, enabling us to confidently advance the development of a commercial BARD1 autoantibody test for ovarian cancer on the Luminex platform. Additionally, the Luminex platform can be applied for development of other tests using our BARD1 autoantibody approach for breast and lung cancers.”

Ovarian cancer is the seventh most commonly diagnosed cancer among women accounting for an estimated 295,414 new cases and 184,799 deaths worldwide annually. A woman’s lifetime risk of developing ovarian cancer is 1 in 75, and her chance of dying of the disease is 1 in 100. The disease typically presents at late stage when the 5-year relative survival rate is only 29%. Earlier detection of ovarian cancer has the potential to enable a stage shift from late to early-stage detection of ovarian cancer when the tumour is localised and the 5-year survival rate is up to 92% (15% cases).[1]

The next step in the development of the BARD1-Ovarian cancer test is to conduct a study using the new RUO BARD1 kits in an independent sample set at an independent laboratory in Australia (MIRG at Griffith University).

BARD1 CSO, Dr Peter French, said: “This is an encouraging result for the commercial development of the BARD1 autoantibody platform approach. I look forward to further developing this assay with founding scientist Dr Irmgard Irminger-Finger, her team at the University of Geneva and independent researchers at Griffith University.”

Previous research (OC-R001 Study) showed the BARD1-Ovarian cancer test could accurately detect ovarian cancer in high-risk women with a family history of ovarian cancer or BRCA1/2 mutations. Other research (BC-001 Study) showed the BARD1-Breast cancer test could accurately detect breast cancer and distinguish it from healthy controls and benign tumours in samples from average-risk women. Recent follow-up research (BC-002 Study) confirmed that the BARD1-Breast cancer test could also accurately detect breast cancer in high-risk women with BRCA1/2 mutations.

Women with BRCA1/2 mutations have an increased lifetime risk of developing breast cancer of up to 72% and ovarian cancer of up to 44%.[2] Clinical guidelines recommend that high-risk women (including family history, BRCA1/2 mutations and other factors) be screened regularly for breast/ovarian cancer.[3,4]

BARD1 Founding Scientist and Executive Director, Dr Irmgard Irminger-Finger, said: "The BARD1 splice variant proteins play an important role in cancer progression and prognosis. My vision is to develop accurate and reliable BARD1 autoantibody tests for early detection of breast and ovarian cancers with the potential to significantly improve treatment, health and survival outcomes for this important unmet clinical need in women's health."

The Company plans to further develop the BARD1-Ovarian and BARD1-Breast cancer tests on the Luminex platform to determine their potential as non-invasive screening tools in high-risk women for early detection of ovarian and breast cancers. This will involve finalisation of the development plan for screening of high-risk women for both breast/ovarian cancers, collection of biospecimens, and additional optimisation and clinical validation studies of the BARD1 tests on the Luminex platform.

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 BARD1 AUTOANTIBODY TESTS

The BARD1 autoantibody tests are blood tests in development for early detection of ovarian, breast and lung cancers in high-risk individuals. The tests measure autoantibodies to variant BARD1 proteins in the blood and use a proprietary cancer-specific algorithm to combine these levels into a cancer score that identifies the presence or absence of a specific cancer.

ABOUT OVARIAN CANCER

Ovarian cancer was the seventh most common cancer in women, the leading cause of gynaecological cancer death, and was responsible for 5% of all female cancer deaths worldwide with 295,414 new cases and 184,799 deaths in 2018.[5] There are currently no screening tests recommended for ovarian cancer, which is often diagnosed at a late-stage after symptoms have occurred. The 5-year survival rate of the disease is only 47%.There is a clear unmet clinical need for an accurate and reliable blood test for the early detection and monitoring of ovarian cancer.

ABOUT BREAST CANCER

Breast cancer is the second most commonly diagnosed cancer and leading cause of cancer deaths in women worldwide, with around 2.1 million new cases diagnosed and 626,679 deaths in 2018.[6] For women aged 40 - 74 who participate in screening every 1 - 2 years, the 5-year survival rate is approximately 90% due to mammography screening, increased awareness and improved treatments. However, mammography screening can cause harm through exposure to radiation, false-positive test results and overdiagnosis of biologically benign lesions.[7,8] There is a clear unmet clinical need for an accurate and reliable blood test for the early detection and monitoring of breast 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] Cancer Biol Med. 2017 Feb; 14(1): 9–32.
[2] *JAMA.* 2017;317(23):2402-2416. doi:10.1001/jama.2017.7112
[3] ACS. ACS Recommendations for the Early Detection of Breast Cancer. https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/american-cancer-society-recommendations-for-the-early-detection-of-breast-cancer.html (accessed Sep 21, 2020).
[4] ACS. Can Ovarian Cancer be found early? https://www.cancer.org/cancer/ovarian-cancer/detection-diagnosis-staging/detection.html (accessed Sep 21, 2020).
[5] IARC. GLOBOCAN 2018: Cancer Fact Sheets: Ovary. https://gco.iarc.fr/today/data/factsheets/cancers/25-Ovary-fact-sheet.pdf (accessed Sep 21, 2020).
[6] IARC. GLOBOCAN 2018: Cancer Fact Sheets: Breast. http://gco.iarc.fr/today/data/factsheets/cancers/20-Breast-fact-sheet.pdf (accessed Sep 21, 2020).
[7] ACS. Limitations of Mammograms. https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/mammograms/limitations-of-mammograms.html (accessed Sep 21, 2020).
[8] NIH. Cancer Stat Facts: Female Breast Cancer. Available https://seer.cancer.gov/statfacts/html/breast.html (accessed Sep 21, 2020).