BARD1 ANNOUNCES DEVELOPMENT OF WORLD-FIRST BARD1 BREAST CANCER TEST

- **BARD1 announces development of world-first blood test for early detection of breast cancer**
- **Targeting US$20b global market for breast cancer diagnostics**
- **BARD1 Breast Cancer test has high diagnostic accuracy for detection of breast cancer with AUC 0.86, 70% sensitivity and 88% specificity**
- **BARD1 Breast Cancer accurately detects the two common breast cancer types and distinguishes malignant from benign lesions**
- **BARD1 Breast Cancer test uses the same diagnostic platform as the previously announced BARD1 Ovarian Cancer test – enabling faster development and parallel clinical testing**
- **BARD1 Breast Cancer test addresses an unmet need for effective screening of breast cancer and assessment of benign lesions from breast cancer to detect cancer early, save women's lives and avoid unnecessary surgery**
- **Combination of BARD1 Breast and BARD1 Ovarian Cancer tests provide a tool for monitoring and early detection of cancer in high-risk women with familial accumulation of breast/ovarian cancers or identified mutations in the BRCA1/2 genes**

Perth, Australia, 23 October 2018: BARD1 Life Sciences Limited (ASX:BD1), a biotechnology company developing non-invasive cancer diagnostics, is pleased to announce a world-first BARD1 Breast Cancer (BC) test for early detection of breast cancer.

This breakthrough research shows that the BARD1 BC test has high diagnostic accuracy for detection of breast cancer across all sub-types and stages with AUC 0.86, 70% sensitivity and 88% specificity.

Importantly, BARD1 BC accurately distinguishes malignant breast cancer from benign lesions.

The BARD1 BC breakthrough follows the earlier announcement of success with the BARD1 Ovarian Cancer test. The Company now plans to develop both tests in parallel using the same Luminex instrumentation platform.

There is currently no blood test available for screening or early detection of breast cancer. BARD1 BC could be used to screen average-risk asymptomatic women to detect breast cancer earlier, increase screening uptake, improve survival and reduce healthcare costs.

Additionally, BARD1 BC could be used as a diagnostic aid to assess the risk of malignancy of suspicious lesions detected by mammography to determine if a lesion is benign or malignant. Currently this can only be achieved with biopsies followed by histopathology-based diagnosis.

BARD1 CEO Dr Leearne Hinch said: "The new BARD1 Breast Cancer test addresses an unmet need for an accurate, reliable and affordable blood test to detect breast cancer early.

"The global breast cancer diagnostics market was the second largest diagnostic segment (after lung cancer) valued at US$20.1 billion in 2013 and is expected to grow at 8.8% annually to reach US$36.4 billion by 2020[1], representing a significant global market opportunity for an effective breast cancer screening test.

"BARD1 already has a development program for the game-changing BARD1 Ovarian Cancer test which has shown excellent diagnostic accuracy for early detection of ovarian cancer.

"The new BARD1 Breast Cancer test is a world-first blood test in development for early detection of breast cancer, has demonstrated high diagnostic accuracy to detect breast cancer across common breast cancer types and all stages, and is based on the same BARD1 autoantibody test methodology and Luminex

instrumentation enabling fast development and clinical testing in parallel with the BARD1 Ovarian Cancer test."

Complement to BRCA1/2 genetic testing in high-risk women

Most breast cancers (85%) occur in average-risk women (with no family history of breast cancer) with a lifetime risk of developing breast cancer of 12.4%. About 15% of breast cancers show a familial accumulation (mother, sister or daughter with breast cancer) that nearly doubles the lifetime risk, and 5-10% are associated with inherited mutations in breast cancer predisposition genes. Hereditary breast cancer is most frequently associated with mutations in the BRCA1/2 genes, with a 45-65% lifetime risk of developing breast cancer, and a 10-70% risk of developing ovarian cancer for mutation carriers.[2,3]

Genetic testing for BRCA1/2 mutations is recommended and often reimbursed for women with a family history of breast/ovarian cancers to determine if a woman is a carrier of mutations and at higher lifetime risk of developing breast/ovarian cancer. However, genetic tests do not detect if a woman has breast or ovarian cancer. Clinical guidelines recommend that women with a positive BRCA1/2 test should undergo regular exams for breast/ovarian cancer development (mammography for breast and transvaginal ultrasound for ovarian cancer) or elect preventative surgery to remove breasts and ovaries after the childbearing age. *The BARD1 Breast and BARD1 Ovarian Cancer tests could follow BRCA1/2 genetic testing and provide the tool that makes it possible to regularly monitor high-risk women to detect cancer early, save lives and avoid unnecessary surgery.*

BARD1 Executive Director and Chief Scientific Officer Dr Irmgard Irminger-Finger said: "Women with identified mutations in BRCA1/2 would undergo BARD1 Breast/Ovarian Cancer tests and only if cancer is detected they would be directed to further testing (mammography, transvaginal ultrasound, biopsies, etc.) to determine the best treatment pathway.

"Women identified positively for BRCA1/2 mutations and negative for BARD1 tests should be advised to undergo BARD1 Breast/Ovarian tests in six-monthly intervals to enable early detection of breast or ovarian cancer.

"Women with a negative BRCA1/2 test could be recommended to annual or biannual screening with the BARD1 Breast/Ovarian Cancer test."

Following these excellent results, BARD1 plans to conduct additional breast cancer studies to further develop, optimize and evaluate BARD1 BC for early detection of breast cancer in larger cohorts comprising different breast cancer types and stages, benign breast lesions, and healthy controls to further improve the diagnostic accuracy of BARD1 BC for early detection of breast cancer.

Breast cancer study shows high accuracy of BARD1 Breast Cancer test for early detection

BARD1 conducted the BC-001 study to develop and evaluate the accuracy of a new BARD1 BC test using a 20 BARD1 peptide panel to detect autoimmune antibodies in 174 serum samples comprising 61 breast cancers, 64 healthy controls and 49 benign breast lesions.

The BC-001a study developed a model for BARD1 BC built on samples of breast cancer and healthy controls and demonstrated its high diagnostic accuracy for detection of breast cancer across all cancer stages with an average AUC=0.95 in training sets and an average AUC=0.86, 70% sensitivity and 88% specificity in the cross-validation test sets.

The sensitivity of BARD1 BC for detection of common breast cancer sub-types invasive ductal cancer (IDC) and invasive lobular cancer (ILC) was further analysed. BARD1 BC could detect IDC with 83% sensitivity and ILC with 100% sensitivity at fixed cutoff of 90% specificity.

The BC-001b study validated the accuracy of BARD1 BC in an independent sample set of 49 benign breast lesions. The results showed that BARD1 BC had 85% sensitivity and 76% specificity for distinction of breast cancer from benign breast lesions at the Youden cutoff. Table 1 summarises the results of the BC-001 case-control study including AUC, sensitivity and specificity.

Table 1: BARD1-Breast test results in BC-001 study

Study	Samples	Training Sets*			Test Sets*		
	n (cancer:control)	AUC	Sensitivity	Specificity	AUC	Sensitivity	Specificity
BC-001a[4] (model and validation)	123 (61:64)	0.94	91%	97%	0.86	70%	88%**
BC-001b (benign comparison)	110 (61:49)				0.84	85%	76%**

** Youden cutoff that maximises sensitivity and specificity*

***Unadjusted specificity that may be adjusted higher to account for up to 12% unidentified breast cancers in controls*

The study concluded that the BARD1 Breast Cancer test showed high accuracy for detection of breast cancer in women across the common cancer subtypes and all stages and could accurately distinguish malignant breast cancer from both healthy controls and benign breast lesions with high specificity. BARD1 BC could be further developed as a screening test for early detection of breast cancer in asymptomatic women, or as a diagnostic aid to determine if a lesion is malignant or benign following a mammogram.

About breast cancer and early detection

Breast cancer is the most common cancer in women and second leading cause of cancer overall (after lung cancer) worldwide, with around 2.1 million new cases diagnosed and 626,679 deaths in 2018.[5] The incidence rates (% new cases) of breast cancer are highest in Australia, Western Europe, Northern Europe and North America.[6]

Breast cancer is currently detected using regular screening with mammography in the US, Europe and Australia. The American Cancer Society's screening recommendations for breast cancer in average-risk, asymptomatic women are optional mammograms for women aged 40-44 years, annual mammograms for women aged 45-54 years, and annual or every second year mammograms for women over 55 years to detect cancer early, whereas recommendations for high-risk women (family history, BRCA1/2 mutations or previous chest radiation therapy) are screening with mammography and MRI annually from age 30 years on.[7]

Breast cancer death rates have steadily decreased due to earlier detection through government screening programs using mammograms (detects cancer earlier when small and not spread), increased awareness and better treatments resulting in an overall 5-year survival rate in women of 90.2% in the USA, 89.5% in Australia and 87% in the UK.[8] Mammograms are the best breast cancer screening test currently available but have limitations including acceptance and compliance with 50-73% uptake, issues with false negatives and false positives (particularly in women with dense breast tissue) resulting in missed diagnosis, anxiety, overdiagnosis and overtreatment, and not all women being eligible or having access due to costs, inconvenience or unavailability particularly in developing countries.[9,10]

Corporate opportunities

Based on its proprietary BARD1 tumour marker platform, the Company now has three BARD1 autoantibody tests in development for ovarian, breast and lung cancers. BARD1 now plans focus its efforts on the parallel development and commercialization of both its BARD1 Ovarian and new BARD1 Breast Cancer tests to take advantage of synergies over the next 2 years with market launch of both tests expected by early 2021. The Company also intends to advance its BARD1-Lung program and to expand applications for its BARD1 tumour marker platform to early detection of other cancers.

BARD1 will engage with leading gynecological/surgical oncologists, research clinicians and biostatisticians to prepare its clinical testing plan for early detection of both breast and ovarian cancers and to initiate prospective collection of biospecimens to enable rapid commencement of clinical studies in 2019 upon the successful transfer of the research-grade BARD1 autoantibody test to the Luminex instrumentation.

Importantly, these exciting new research results in breast cancer further validate the company's biomarker platform, ability to expand the diagnostic pipeline to other cancers with unmet needs and the commercial potential of BARD1's diagnostic assets to investors and partners.

With these new results, BARD1 will continue to advance discussions with its potential corporate and financial partners to build the Company and speed development and commercialisation of its diagnostic assets to maximize value for shareholders.

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ABOUT BARD1 LIFE SCIENCES LTD

BARD1 Life Sciences Ltd (ASX:BD1) is an Australian-based biotechnology company focused on developing and commercialising non-invasive diagnostic tests for early detection of cancer. BARD1's proprietary technology platform is based on novel tumour markers with potential diagnostic and therapeutic applications across multiple cancers. The pipeline includes BARD1 autoantibody tests in development for early detection of breast, ovarian and lung cancers. Additional diagnostic projects will be evaluated for other cancers. The company also has a cancer vaccine project at research-stage for treatment of cancer. BARD1 is committed to transforming the early detection of cancer to save lives. For more information on BARD1, see www.bard1.com.

ABOUT THE BARD1-BREAST CANCER TEST

BARD1-Breast is a blood test in development for early detection of breast cancer. The test measures BARD1 autoantibodies in the blood and uses a proprietary breast cancer-specific algorithm to combine these levels into a cancer score that identifies the presence or absence of breast cancer. BARD1-Breast could potentially be used as a screening test for early detection of breast cancer in asymptomatic women, or as a diagnostic aid to assess the risk of malignancy following inconclusive mammography test results.

ABOUT BREAST CANCER

Breast cancer is the most common cancer and leading cause of cancer deaths in women and second leading cause of cancer overall (after lung cancer) worldwide, with around 2.1 million new cases diagnosed and 626,679 deaths in 2018.[5] The incidence rates of breast cancer are highest in Australia, Western Europe, Northern Europe and North America.[6] In the United States there were about 266,120 (15.3%) new cases diagnosed and 40,920 (6.7%) deaths in women in 2018.[11] Breast cancer death rates have steadily decreased due to earlier detection through government screening programs using mammograms, increased awareness and better treatments resulting in an overall 5-year survival rate in women of 90.2% in the USA, 89.5% in Australia and 87% in the UK.[8] Mammograms are the best breast cancer screening tests currently available but have limitations including false negatives and false positives (particularly in women with dense breast tissue) resulting in missed diagnosis, anxiety, over diagnosis and over treatment.[9,10] There is a clear unmet clinical need for an accurate, reliable and affordable blood test for the early detection and monitoring of breast cancer. The global breast cancer diagnostics market was valued at US$20.1b in 2013 and is expected to grow at 8.8% annually to reach US$36.4b by 2020.[1]

ABOUT DIAGNOSTIC TEST RESULTS

The performance of a diagnostic test can be measured by "AUC", "sensitivity" and "specificity". AUC (area under the curve) is an overall score of diagnostic accuracy generated by a ROC (receiver operating characteristic) curve, where a perfect test would have an AUC=1.0, an excellent test AUC=0.9-0.99, a good test AUC=0.8-0.89, and a useless test AUC=0.5. Sensitivity is the percent of patients with cancer correctly identified positive (true positive rate) and specificity refers to the percent of patients without cancer correctly identified negative (true negative result). A good diagnostic test must demonstrate acceptable sensitivity and false positives rates for its intended use.

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[4] BARD1 LSL. BC-001 Study. Data on file. Oct 2018
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