BARD1 ANNOUNCES IMPROVED PERFORMANCE OF BARD1-OVARIAN TEST

- **BARD1-Ovarian test significantly improved by addition of the CA125 biomarker to the BARD1 algorithm**
- **Results showed excellent accuracy of the improved BARD1-Ovarian test for detection of ovarian cancer with 88% sensitivity and 93% specificity in test sets**
- **Study validates the potential of the improved BARD1-Ovarian test to be further developed as a screening test for ovarian cancer with low false positives**

Perth, Australia, 19 June 2018: BARD1 Life Sciences Limited (ASX:BD1), a biotechnology company developing non-invasive cancer diagnostics, today announced positive results from an improved BARD1-Ovarian test that demonstrated excellent diagnostic accuracy of AUC 0.95, 88% sensitivity and 93% specificity for detection of ovarian cancer in test sets.

BARD1 conducted the OC-CA125 study to evaluate and compare the accuracy of the original BARD1 algorithm alone, CA125 alone, and the combined BARD1-CA125 algorithm to detect ovarian cancer in 200 ovarian cancers and 200 healthy controls.

The results demonstrated that the combined BARD1-CA125 algorithm outperformed the BARD1 algorithm alone and CA125 alone for detection of ovarian cancer. The combined BARD1-CA125 algorithm had excellent diagnostic accuracy with an average AUC 0.98 in training sets, and an average AUC 0.95, 88% sensitivity and 93% specificity in test sets (at Youden cutoff). Addition of CA125 to the BARD1-Ovarian test increased sensitivity for detection of ovarian cancer by 6% and specificity by 14% over the previously reported OC-400 study results for the BARD1 algorithm alone (Table 1).

Table 1: BARD1-Ovarian test results in OC-400 and OC-CA125 Studies

Study	Samples	Training Sets*			Test Sets*		
	n (cancer:normal)	AUC	Sensitivity	Specificity	AUC	Sensitivity	Specificity
OC-400 Study[1]	400 (200:200) Cross-validation	0.92	90%	85%	0.88	82%	79%
OC-CA125 Study[2]	400 (200:200) Cross-validation	0.98	90%	98%	0.95	88%	93%

* *Youden cutoff that maximises sensitivity and specificity*

The study concluded that the accuracy of the BARD1-Ovarian test was significantly improved ($\rho<0.05$) by the addition of CA125 to the algorithm. The high sensitivity and low false positive rate of the improved BARD1-Ovarian test demonstrated its potential to be further developed as a screening test for ovarian cancer in asymptomatic women and/or as an aid in the diagnosis of ovarian cancer in symptomatic women.

BARD1 Executive Director and CSO, Dr Irmgard Irminger-Finger, said "CA125 values correlate with tumour burden and more accurately detect late-stage cancer, whereas BARD1 autoantibodies reflect the early immune response to tumour formation and are present from early to late-stage cancer, hence the BARD1-CA125 combination is presumed to more accurately detect early and late stages. This study confirmed that addition of CA125 to the BARD1-Ovarian test, improved its sensitivity across all stages and reduced false positives. Our goal is to develop BARD1-Ovarian as an accurate and reliable screening test for early detection of ovarian cancer when it can be potentially cured and help save women's lives."

Professor Robert Zeillinger at the Medical University of Vienna Austria assessed the OC-CA125 Study and said: "The results of the study presented by BARD1 Life Sciences, with a AUC=0.95 in test sets, surpass those for previously reported biomarkers. Therefore, the combined BARD1 OC-CA125 algorithm

[1] BARD1 LSL. OC-400 Study. Data on file. Jan 2018
[2] BARD1 LSL. OC-CA125 Study. Data on file. Jun 2018

has the potential to replace other tests that are currently available and become the state of the art test especially for early stage ovarian cancers."

Upon successful completion of the Assay Development project to transfer the research BARD1 assay to the ProcartaPlex® Technology, BARD1 intends to conduct clinical studies to evaluate the clinical performance of BARD1-Ovarian for screening and diagnosis of ovarian cancer.

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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 development pipeline includes two BARD1 autoantibody tests in development for early detection of lung and ovarian cancers, and a cancer vaccine project at research-stage for treatment of cancer. Additional diagnostic projects are being evaluated for prostate, breast and other cancers. BARD1 is committed to transforming the early detection and prevention of cancer to help improve patients' lives. For more information on BARD1, see www.bard1.com.

ABOUT THE BARD1-OVARIAN TEST

BARD1-Ovarian is an ELISA-based blood test in development for early detection of ovarian cancer. 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 reflect tumour burden and are 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.

ABOUT OVARIAN CANCER

Ovarian cancer is the leading cause of gynaecological cancer deaths and seventh most common cancer in women worldwide, with around 239,000 new cases diagnosed and 152,000 deaths in 2012.[3] 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 46% 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 29% to 92%, a potential survival improvement of 3 times. There is a clear unmet clinical need for non-invasive, accurate and affordable diagnostic tests for the early detection and monitoring of ovarian

[3] Ferlay J, et al. GLOBOCAN 2012 v1.0, Estimated Incidence, Mortality and 5-year Prevalence: IARC CancerBase No. 11 [Internet]. Lyon, France: IARC; 2013. Available: http://globocan.iarc.fr/Pages/fact_sheets_population.aspx

cancer. The global ovarian cancer diagnostics market was valued at US$7.2B in 2013 and is expected to grow at 7.2% annually to reach US $11.8B by 2020[4].

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.

ABOUT PROFESSOR ROBERT ZEILLINGER PhD

Professor Robert Zeillinger PhD is head of the Molecular Oncology Group, Department for Obstetrics and Gynaecology, at the *Medical University of Vienna*, Austria. Professor Zeillinger has over 30 years’ experience in both academic and industrial research, he is a renowned scientist and proven leader of interdisciplinary, multinational teams. His distinguished scientific expertise is complemented by extensive experience in coordinating research projects of the EC-framework programmes FP6 and FP7. He is author and co-author of more than 200 scientific publications and holds several patents.

Professor Zeillinger’s key research interests include clinical studies to evaluate markers for the detection of ovarian cancer. His company *OncoLab Diagnostics GmbH* is currently developing tests based on the results of his work (see https://www.ncbi.nlm.nih.gov/pubmed/?term=Zeillinger+R). Professor Zeillinger advises that in the long term we need to develop a test for population-wide screening of ovarian cancer with a specificity of 99.6%. However, a specificity of 95% is regarded as sufficient for discriminating benign from malignant masses.

[4] Transparency Market Research (2014, Oct 31). *Cancer Diagnostics Market: Global Industry Analysis, Size, Share, Growth, Trends, Forecast, 2014 - 2020*. Available http://www.transparencymarketresearch.com/cancer-diagnostics-market.html, accessed October 15, 2016.