BARD1 ANNOUNCES POSITIVE RESULTS FROM OC-400 STUDY OF BARD1-OVARIAN TEST

- **Successful completion of OC-400 Study to evaluate the accuracy of BARD1-Ovarian for detection of ovarian cancer using the POC method**
- **Results showed high accuracy of BARD1-Ovarian with an average AUC 0.92 in training sets, and an average AUC 0.88, 82% sensitivity and 79% specificity in test sets**
- **Study concluded that BARD1-Ovarian accurately detected ovarian cancer, and confirmed its potential to be further developed into a commercial test for early detection of ovarian cancer**

Perth, Australia, 9 January 2018: BARD1 Life Sciences Limited (ASX:BD1), a biotechnology company developing non-invasive cancer diagnostics, today announced positive results from its OC-400 Study that showed BARD1-Ovarian achieved high accuracy for detection of ovarian cancer with an average AUC (area under the curve) of 0.92 in the training sets, and an average AUC of 0.88, 82% sensitivity and 79% specificity in the test sets.

BARD1 has successfully completed the retrospective, case-control, OC-400 Study to evaluate the accuracy of the multi-analyte BARD1-Ovarian test to detect ovarian cancer in 400 female bio-banked samples of ovarian cancer and aged-matched healthy controls. The objectives of the study were to optimise the BARD1 panel and algorithm used in BARD1-Ovarian for early detection of ovarian cancer and to evaluate the accuracy of the test using the POC (proof-of-concept) method[1] on a panel of 20 peptides (analytes).

Data analysis generated a model with an average AUC of 0.92, 90% sensitivity and 85% specificity in the training sets, and an average AUC of 0.88, 82% sensitivity and 79% specificity in the cross-validation test sets. Table 1 summarises the results of BARD1-Ovarian in the OC-400 Study including AUC, sensitivity and specificity.

Table 1: BARD1-Ovarian test results in OC-400 Study

Study	Samples	Training Sets			Test Sets		
	n (cancer:normal)	AUC	Sensitivity	Specificity	AUC	Sensitivity	Specificity
OC-400 Study[2]	400 (200:200)	0.92	90%	85%	0.88	82%	79%

** Independent test set analysis*

The results of the OC-400 Study confirmed previous study findings that BARD1-Ovarian could accurately detect ovarian cancer with high sensitivity and specificity. Importantly, these results were achieved using less analytes reducing the complexity and cost of the BARD1-Ovarian test, which may offer improved performance over the CA125 blood test that is routinely used as a diagnostic aid for ovarian cancer.

The study concluded that BARD1-Ovarian accurately discriminated ovarian cancer from healthy controls using the POC method and a 20-analyte panel, could detect all subtypes and stages of ovarian cancer, and confirmed the potential of the research-grade test to be further developed into a commercial test with expected high sensitivity and specificity for early detection of ovarian cancer.

BARD1 Executive Director and CSO, Dr Irmgard Irminger-Finger, said “this study showed that using the POC method, BARD1-Ovarian achieved better sensitivity and specificity in a sample set from multiple-sites with a reduced number of analytes than previously reported in the OC-300 Study.”

[1] Pilyugin M, Descloux P, André P-A, Laszlo V, Dome B, Hegedus B, et al. (2017) BARD1 serum autoantibodies for early detection of lung cancer. PLoS ONE 12(8): e0182356. https://doi.org/10.1371/journal.pone.0182356

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

"The positive results achieved in this OC-400 Study confirmed the potential of BARD1-Ovarian to accurately detect ovarian cancer with high sensitivity and specificity," said Dr Leearne Hinch, BARD1 CEO. "The reduced analyte panel is an important step forward in the development of an accurate and affordable BARD1-Ovarian test for early detection of ovarian cancer."

BARD1 intends to advance the development of BARD1-Ovarian for early detection of ovarian cancer including outsourcing further assay development to a contract development organisation to build a commercial test, complete technical validation, and undertake clinical validation studies to demonstrate its clinical performance and support future marketing and/or licensing of the test.

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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 early 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. Preliminary results from pilot studies indicate the high accuracy of BARD1-Ovarian for detection of ovarian cancer with up to 92% sensitivity and 84% specificity. 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 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 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].

[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

[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.

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 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 REPEATED RANDOM SUB-SAMPLING CROSS-VALIDATION

Cross-validation is a statistical method to evaluate the predictive performance of a model. In repeated random sub-sampling cross-validation, the samples are randomly split into 3/4 training sets to train the algorithm and 1/4 test sets to evaluate the algorithm, and the process repeated 200 times. The performance of the algorithm is then evaluated by computing the average AUC, sensitivity and specificity in the test sets.