BARD1 ANNOUNCES ADDITIONAL POSITIVE RESULTS USING BARD1-OVARIAN TEST IN FOLLOW-ON STUDY

- **Successful application of BARD1-Ovarian test to an independent sample set of 82 new ovarian cancers and 27 healthy controls**
- **Results showed high accuracy of BARD1-Ovarian for detection of ovarian cancer with 89% sensitivity and 82% specificity in an independent test set**
- **Study confirmed the robustness and potential utility of BARD1-Ovarian as a diagnostic aid for early detection of ovarian cancer**

Perth, Australia, 6 March 2018: BARD1 Life Sciences Limited (ASX:BD1), a biotechnology company developing non-invasive cancer diagnostics, today announced additional positive results from application of its BARD1-Ovarian test to an independent test set confirming high accuracy for detection of ovarian cancer with 89% sensitivity and 82% specificity.

BARD1 conducted a follow-on OC-400V study to evaluate the robustness of the BARD1-Ovarian algorithm generated in the OC-400 Study to detect ovarian cancer in an independent test set of 82 new ovarian cancers and 27 previously tested healthy controls.

The results of this OC-400V study showed high accuracy for detection of ovarian cancer with 89% sensitivity and 82% specificity in the independent test set. Importantly, these results compare favourably to the results previously reported in the OC-400 Study of 82% sensitivity and 79% specificity in the cross-validation test sets. Table 1 summarises the results of BARD1-Ovarian in the OC-400 Study and follow-on OC-400V Study including AUC, sensitivity and specificity.

Table 1: BARD1-Ovarian test results in OC-400 and OC-400V 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-400V Study[2]	109 (82:27) Independent validation				0.89	89%	82%

** Youden cutoff that maximises sensitivity and specificity*

The study concluded that BARD1-Ovarian could be successfully applied to an independent test set and confirmed its robustness and potential utility as a diagnostic aid for early detection of ovarian cancer.

BARD1 Executive Director and CSO, Dr Irmgard Irminger-Finger, said "This study provides further evidence of the robustness of the BARD1-Ovarian test. Upon transfer to a commercial platform, our ongoing product development efforts will focus on testing BARD1-Ovarian in larger sample sets and the addition of other immunogenic markers to our biomarker panel to further train the algorithm and increase its accuracy for early detection of ovarian cancer."

BARD1 is currently in discussions with a number of contract laboratory organisations that have specialty expertise in assay development and validation to transfer the BARD1 research essay to a commercial platform that will enable the BARD1 tests to be performed by most hospital and independent clinical laboratories around the world. "BARD1 anticipates that transfer of our research assay to a commercial platform will enable more efficient development and commercialisation of our diagnostic pipeline for detection of lung, ovarian and other cancers," said Dr Leearne Hinch, BARD1 CEO.

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

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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. 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].

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.

[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.