

SUCCESSFUL ASSAY FEASIBILITY RESULTS

Perth, Australia, 8 February 2017: Australian life sciences company BARD1 Life Sciences Limited (ASX:BD1) (**BARD1 LSL** or the **Company**) today announced successful results from its Assay Feasibility Study.

Highlights

- Assay Feasibility Study completed: Study to evaluate the BARD1 Lung Cancer Test on a commercial instrument platform for research use only was completed in December 2016.
- **Results comparable to previous POC study:** Statistical analysis of the data yielded a ROC-AUC = 0.93, which was comparable to the ROC-AUC = 0.96 previously reported for the POC Study.
- Final Report confirms feasibility: MSD data confirms BARD1 Lung Cancer Test can be performed on a commercial-scale MSD instrument platform using a standardised method.

BARD1 LSL commenced Analytical Validation in August 2016 to further develop, optimise and validate the BARD1 Lung Cancer Test for detection of lung cancer. Meso Scale Diagnostics, LLC. (MSD) was engaged to transfer, optimise and validate the BARD1 Test on its commercial instrument platform for research use only.

MSD conducted an Assay Feasibility Study to evaluate the research-grade BARD1 Lung Cancer Test on its instrument platform. MSD tested 40 lung cancer and control samples across 40 BARD1 peptides using various coating methods and dilution factors to determine the best assay method for further development of a clinical-grade BARD1 Lung Cancer Test.

MSD completed the study and provided the raw data to the Company for analysis in December 2016. Statistical analysis and modelling by the University of Geneva (UNIGE) showed that at least one method reproduced a similar receiver operating characteristic (ROC)-area under the curve (AUC) = 0.93¹ (see Figure 1) to that previously reported in the Proof of Concept (POC) Study of ROC-AUC = 0.96².

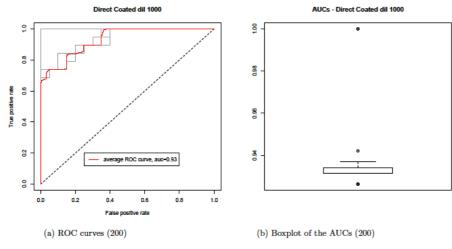


Figure 1. Receiver operating characteristic (ROC) curves (a) and area under the curve (AUCs) (b) obtained by Lasso Linear Regression modelling using the whole dataset of the best method for distinction of lung cancer and control samples. The variability is due to the statistical internal cross-validation procedure used for selecting the regularization parameter.

The Final Report by MSD confirms the reproducibility of the BARD1 Lung Cancer Test in an independent laboratory on a commercial research use only instrument platform³. And analysis of the MSD data confirms the feasibility of transferring the research-grade BARD1 Lung Cancer Test to this platform.

² Data on file. Lung Cancer POC Study. 2014.

¹ Data on file. Statistical Report. Jan 2017.

³ MSD. BARD1 Final Report on Assay Feasibility Study. Feb 2017.

Further assay optimisation and validation testing of defined specifications will be required to develop a final BARD1 Lung Cancer Test on the MSD instrument platform³.

Executive Director and Chief Scientific Officer, Dr Irmgard Irminger-Finger said "I am delighted that these results demonstrate the potential of developing a standardised BARD1 Lung Cancer Test that can be performed on a commercial instrument platform to enable fast, accurate and reliable testing across centralised laboratories."

The Confirmation Study to further develop and optimise the BARD1 Lung Cancer Test across 530 samples of lung cancer and healthy controls has been completed, analysis is underway, and results are expected to be announced by end of March 2017.

BARD1 LSL is focused on advancing the development of the BARD1 Lung Cancer Test for screening and diagnosis of lung cancer. BARD1 LSL plans to conduct a prospective study to demonstrate the accuracy, sensitivity and specificity of the BARD1 Lung Cancer Test compared to computed tomography (CT) scans for early detection of lung cancer in high-risk individuals. The planned prospective study is expected to commence in the second half of calendar year 2017.

- ENDS -

FOR MORE INFORMATION PLEASE CONTACT:

Peter Gunzburg Dr Leearne Hinch

Chairman CEO

E <u>peter@bard1.com</u>

E <u>leearne@bard1.com</u>

M +61 400 414 416

ABOUT BARD1 LIFE SCIENCES LTD (BARD1 LSL)

BARD1 Life Sciences Ltd (ASX:BD1) is an Australian life sciences company developing novel diagnostics and therapeutics for unmet needs in cancer. The BARD1 technology platform includes proprietary, proven and specific cancer biomarkers, diagnostic algorithms and assays. Its lead product the BARD1 Lung Cancer Test is a non-invasive blood test in development for early detection of lung cancer. It is also researching a high-value pipeline of potential diagnostic and therapeutic products for multiple cancers. BARD1 is committed to transforming the early detection and prevention of cancer to help improve patients' lives.

ABOUT BARD1 LUNG CANCER TEST

The BARD1 Lung Cancer Test is a simple, non-invasive blood test in development for early detection of lung cancer. The test detects BARD1 autoantibodies that are released from cancer cells into the blood, even from early-stage tumours, making the BARD1 Test potentially more accurate for screening and diagnosis of early-stage lung cancer. Preliminary results indicate that the BARD1 Lung Cancer Test will have sensitivity greater than 90% and false positives less than 10% for lung cancer. The BARD1 Lung Cancer Test can be potentially used as a screening test for early detection of lung cancer in high-risk individuals that are asymptomatic, or as a diagnostic aid for detection of lung cancer in symptomatic individuals or to confirm a suspicious CT Scan.

ABOUT LUNG CANCER

Lung cancer is the most common cancer and leading cause of death worldwide, with an incidence of 1.82M new cases and 1.59M deaths⁴. Lung cancer is often diagnosed at a later stage after symptoms have appeared, resulting in a poor prognosis with an average 5-year survival of 5.8% worldwide. There is a clear market need for accurate and reliable diagnostic tests for the early detection of lung cancer. The global lung cancer diagnostics market was valued at US \$26.0B in 2013 and is expected to grow at 7.1% annually to reach US \$42.2B by 2020⁵.

⁴ Ferlay J, et al. GLOBOCAN 2012 v1.0, Lung Cancer Estimated Incidence, Mortality and Prevalence Worldwide in 2012: IARC CancerBase No. 11 [Internet]. Lyon, France: IARC; 2013. Available: http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx?cancer=lung

⁵ Transparency Market Research. Cancer Diagnostics Market 2014-2020. 2014.