

# BARD1 LUNG CANCER STUDY RESULTS

**Perth, Australia, 15 May 2017:** Australian biotechnology company BARD1 Life Sciences Limited (ASX:BD1) (**BARD1 LSL** or the **Company**) today announced the results of a 638-sample lung cancer study using its research-grade BARD1 Lung Cancer Test. The study demonstrated that the BARD1 Test had an overall ROC-AUC score for accuracy in identifying lung cancer of 0.82 in the training sets and 0.725 in the test sets.

This research study was conducted at Meso Scale Diagnostics, LLC (MSD) using the MSD research-use-only (RUO) instrument platform to detect lung cancer in 638 retrospectively collected samples, across a broad range of lung cancer subtypes and stages. The study aimed to refine both the multi-analyte BARD1 panel and algorithm for the early detection of lung cancer, and to establish the performance characteristics using the MSD platform across different cancer stages and common histological subtypes.

Statistical analysis by external experts demonstrated that the training sets used to develop the model had a receiver operating characteristic (ROC) - area under the curve (AUC) = 0.82, whereas the test sets used to validate the model achieved a lower AUC = 0.725.

BARD1 LSL has identified a combination of technical factors, including changes to the assay and patient cohort, that we believe may have contributed to the reduced performance of the BARD1 Test in this study. The Company is working with scientists, clinical experts, and industry leaders to resolve these issues, and plans to optimise the assay and validate the analytical performance of the BARD1 Test, before entering further clinical validation. BARD1 LSL advises that its planned clinical validation studies for the BARD1 Lung Cancer Test will now be delayed, until completion of the assay development phase and analytical validation.

The same product development and analytical validation steps will apply to the research-grade BARD1 Ovarian Cancer Test, before commencing future clinical validation studies.

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### Notes to editors:

### ABOUT BARD1 LIFE SCIENCES LTD (BARD1 LSL)

BARD1 Life Sciences Ltd (ASX:BD1) is an Australian biotechnology company focused on developing and commercialising non-invasive diagnostic tests for early detection of cancer. Its lead product, the BARD1 Lung Cancer Test, is a blood test in development for early detection of lung cancer, utilising novel tumour markers and a proprietary algorithm. The company's pipeline also includes the BARD1 Ovarian Cancer Test in development for early detection of ovarian cancer, and high-value diagnostic and therapeutic projects at research-stage for multiple cancers. BARD1 LSL is committed to transforming the early detection and prevention of cancer to help improve patients' lives.

## ABOUT THE BARD1 TECHNOLOGY PLATFORM

The proprietary BARD1 Technology includes BARD1 tumour markers, diagnostic assays and algorithms. BARD1 tumour markers have potential utility as 1) diagnostic biomarkers for the detection and monitoring of cancer, and 2) therapeutic targets for immunotherapies that inhibit abnormal BARD1 for the prevention or treatment of cancer. The BARD1 Technology has potential applications across multiple cancers including lung, breast, ovarian, prostate, and colorectal cancer.

BARD1 is both a gene and a protein that plays an important role in the normal cell cycle and tumour suppression. However, cancer cells express numerous abnormal BARD1 proteins that drive oncogenesis (cancer formation), and are correlated with cancer progression and poor prognosis. Abnormal BARD1 proteins are immunogenic and induce circulating BARD1 autoantibodies in the blood. These abnormal BARD1 proteins (tumour-associated antigens) and autoantibodies are tumour markers that can be found in the blood of people with various cancer types and stages from early to late.

# **ABOUT THE BARD1 LUNG CANCER TEST**

The BARD1 Lung Cancer Test is an ELISA-based blood test in development for screening and diagnosis of lung 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 lung cancer. The BARD1 Lung Cancer Test could potentially be used as a screening test for early detection of lung cancer in high-risk asymptomatic individuals, as a diagnostic aid for lung cancer in people with symptoms, or to assess the risk of malignancy in people with indeterminate pulmonary nodules following a 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 deaths<sup>1</sup>. Lung cancer is often diagnosed at a later stage after symptoms have appeared, resulting in a poor prognosis with a low overall 5-year survival rate of 18% in the US. Earlier detection by finding lung cancer when local rather than distant may increase 5-year survival from 4% to 55%, a potential survival improvement of 13 times. There is a clear unmet clinical need for non-invasive, accurate and affordable diagnostic tests for the early detection and diagnosis 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 2020<sup>2</sup>.

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<sup>&</sup>lt;sup>1</sup> 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: <a href="http://globocan.iarc.fr/Pages/fact\_sheets\_cancer.aspx?cancer=lung">http://globocan.iarc.fr/Pages/fact\_sheets\_cancer.aspx?cancer=lung</a>

<sup>&</sup>lt;sup>2</sup> Transparency Market Research (2014, Oct 31). *Cancer Diagnostics Market: Global Industry Analysis, Size, Share, Growth, Trends, Forecast, 2014 - 2020.* Available <a href="http://www.transparencymarketresearch.com/cancer-diagnostics-market.html">http://www.transparencymarketresearch.com/cancer-diagnostics-market.html</a>, accessed October 15, 2016.