

## SHAREHOLDER UPDATE

**Perth, Australia, 18 April 2017:** Australian biotechnology company BARD1 Life Sciences Limited (ASX:BD1) (**BARD1 LSL** or the **Company**) provides the following shareholder update on the status of its Lung Cancer diagnostics program.

BARD1 LSL initiated a 450-subject lung cancer study in late 2016 to evaluate the feasibility of its research-grade BARD1 Lung Cancer Test on the Meso Scale Diagnostics (MSD) research-use-only (RUO) instrument platform, and its performance characteristics across different lung cancer subtypes and stages.

The initial results of the pilot study to set up the BARD1 Lung Cancer Test used 40 samples (20 lung cancer and 20 controls) on the MSD RUO instrument platform and yielded a receiver operating characteristic (ROC)-area under the curve (AUC) = 0.93, thus verifying the reproducibility of the test in this setting (see ASX announcement of 8/2/17).

The Company had previously advised that it had expected to announce the results of its lung cancer study to optimise the performance and determine the limits of the test for detection of lung cancers by the end of March 2017. However, due to the expanded study testing 638 subjects across a broad range of lung cancer subtypes, stages and origins, the data is still undergoing analysis and external expert review to finalise the results, and determine the performance of the BARD1 Test for early detection of lung cancer. The Company will now report the results to the market once this analysis is completed and the final report is available. This process is expected to take up to 8 weeks.

The BARD1 Lung Cancer Test is an ELISA-based blood test in development for the screening and diagnosis of lung cancer. The test measures multiple BARD1 autoantibodies, and uses a proprietary diagnostic algorithm to identify the presence or absence of lung cancer.

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### 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 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>.

## UNDERSTANDING RESULTS IN CANCER DIAGNOSTIC STUDIES

The most important results in any study of a cancer diagnostic test are “sensitivity” and “specificity”. Sensitivity refers to the percentage of accurately identified cancers (true positive rate) and specificity refers to the percentage of correct non-cancers identified (true negative result). A good new generation diagnostic test should have both results in the high range (above 80%). Using such a test would ensure acceptable rates of both false positives and false negatives. An overall score of accuracy of a diagnostic test can be provided by a “ROC-AUC” (Receiver Operating Characteristic - Area Under the Curve). 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.

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<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: [http://globocan.iarc.fr/Pages/fact\\_sheets\\_cancer.aspx?cancer=lung](http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx?cancer=lung)

<sup>2</sup> 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.