OVARIAN CANCER CLINICAL STUDY RESULTS

Perth, Australia, 23 March 2017: Australian biotechnology company BARD1 Life Sciences Limited (ASX:BD1) (**BARD1 LSL** or the **Company**) today announced the successful completion of a clinical trial using its proprietary ovarian cancer diagnostic test. The trial involving 348 samples (200 women with ovarian cancer and 148 controls) found the test to have both high specificity (87%) and high sensitivity (90%), with a high overall Receiver Operating Characteristic (ROC)-Area Under the Curve (AUC) score for accuracy of 0.92. In addition, the test detected all subtypes and stages of ovarian cancer in the samples with the performance of the test between early-stage and late stage ovarian cancer not statistically different (p>0.5).

The BARD1 Ovarian Cancer Test is an ELISA-based blood test that uses a panel of peptides on a solid surface. When exposed to a blood sample the test measures the binding of antibodies in the patient's blood to these peptides. Previous data from smaller scale studies had already established the proof of concept of the test and initial indications of high sensitivity and specificity.

"With high levels of accuracy shown to all stages of ovarian cancer, our test may offer a substantial improvement over existing ovarian cancer blood tests using CA125 where both sensitivity and specificity are lower." said Dr Leearne Hinch, Chief Executive Officer at BARD1 Life Sciences Ltd, "Our test should greatly improve the accurate detection of cancer at all stages with few false positives."

Further studies are planned to demonstrate the use of the BARD1 Ovarian Cancer Test for distinction of benign ovarian lesions and cancer. Additionally, an evaluation of commercial instrument platforms will be undertaken to select the best platform for future clinical validation studies testing large prospective cohorts in a clinical laboratory.

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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 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 OVARIAN CANCER TEST

The BARD1 Ovarian Cancer Test is an ELISA-based blood test in development for detection and monitoring 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 proof of concept (POC) studies indicate that the BARD1 Ovarian Cancer Test may have accuracy over 86%, sensitivity greater than 85% and false positives less than 15% for ovarian cancer. The BARD1 Ovarian Cancer Test could potentially be used as a screening test for early detection of ovarian cancer in high-risk individuals that are asymptomatic, as a diagnostic aid for detection of ovarian cancer in women with pelvic masses, or to monitor ovarian cancer recurrence.

ABOUT OVARIAN CANCER

Ovarian cancer is the seventh most common cancer and fifth leading cause of cancer-related death in women worldwide, with an incidence of 239K new cases and 152K deaths[1]. 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[2].

UNDERSTANDING RESULTS IN CANCER DIAGNOSTIC TRIALS

The most important results in any trial 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 of these scores in the high range (above 80%). Using such a test would ensure very low rates of both false positives or false negatives. An overall score of accuracy can be generated from this and is called “ROC-AUC”. 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.

[1] 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

[2] 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.