BARD1 ANNOUNCES PUBLICATION OF PAPER ON BARD1 LUNG CANCER TEST IN PLOS ONE

- **Publication of study results for BARD1 Lung Cancer Test in international peer-reviewed journal PLOS ONE**
- **Results showed BARD1 Lung Cancer Test achieved AUC 0.96 for best fitted model and AUC 0.86 in independent validation sets**
- **Paper concluded BARD1 Lung Cancer Test could be further developed as a screening test or diagnostic aid for lung cancer**

Perth, Australia, 8 August 2017: Australian biotechnology company BARD1 Life Sciences Limited (ASX:BD1) (**BARD1 LSL** or the **Company**) is pleased to announce the publication in PLOS ONE of a key paper describing the methodology underpinning the BARD1 Lung Cancer Test.

The paper titled 'BARD1 serum autoantibodies for early detection of lung cancer' describes a simple and reliable blood test for early detection of all types of lung cancer based on the immunogenicity of aberrant forms of BARD1 protein that are upregulated in lung cancer. The study evaluates the use of ELISA assays with a panel of BARD1 antigens to detect serum levels of BARD1 antibodies in 194 blood samples from lung cancer patients and healthy controls. Applying Lasso logistic regression analysis for defining the optimal combination of BARD1 antigens showed that the BARD1 Lung Cancer Test achieved high accuracy with an AUC (area under the curve) of 0.96 for the best fitted model and 0.86 in the independent validation sets.[1] The study concluded that the BARD1 Lung Cancer Test showed higher sensitivity and specificity than previously published blood tests for lung cancer detection and could detect all types and stages of lung cancer. Additionally, the BARD1 Lung Cancer Test could be further developed as a screening test for early detection of lung cancers in high risk groups, and as a diagnostic aid complementing CT (computed tomography) scanning.

The paper was accepted for publication in the leading medical science journal PLOS ONE after peer review by experts in the field of the molecular biology of lung cancer and cancer biomarkers. Publication of the study in PLOS ONE is an important step towards gaining wider acceptance of the methodology underpinning the BARD1 Lung Cancer Test developed by Dr Irminger-Finger and her team at the University of Geneva.

Dr Leearne Hinch, BARD1 CEO said: "The Company congratulates Dr Irminger-Finger and her research team for achieving this milestone. Dr Irminger-Finger has now published over 40 papers on the BARD1 biology and science that underpins the intellectual property of the Company, including the BARD1 Lung Cancer Test." A link to the paper will be made available on the BARD1 LSL website www.bard1.com.

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[1] Pilyugin M, Descloux P, André P-A, Laszlo V, Dome B, Hegedus B, et al. (2017) BARD1 serum autoantibodies for early detection of lung cancer. PLoS ONE 12(8): e0182356. https://doi.org/10.1371/journal.pone.0182356

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.

ABSTRACT[1]

Purpose

Currently the screening for lung cancer for risk groups is based on Computed Tomography (CT) or low dose CT (LDCT), however the lung cancer death rate has not decreased significantly with people undergoing LDCT. We aimed to develop a simple reliable blood test for early detection of all types of lung cancer based on the immunogenicity of aberrant forms of BARD1 that are specifically upregulated in lung cancer.

Methods

ELISA assays were performed with a panel of BARD1 epitopes to detect serum levels of antibodies against BARD1 epitopes. We tested 194 blood samples from healthy donors and lung cancer patients with a panel of 40 BARD1 antigens. Using fitted Lasso logistic regression we determined the optimal combination of BARD1 antigens to be used in ELISA for discriminating lung cancer from healthy controls. Random selection of samples for training sets or validations sets was applied to validate the accuracy of our test.

Results

Fitted Lasso logistic regression models predict high accuracy of the BARD1 autoimmune antibody test with an AUC=0.96. Validation in independent samples provided and AUC=0.86 and identical AUCs were obtained for combined stages 1-3 and late stage 4 lung cancers. The BARD1 antibody test is highly specific for lung cancer and not breast or ovarian cancer.

Conclusion

The BARD1 lung cancer test shows higher sensitivity and specificity than previously published blood tests for lung cancer detection and/or diagnosis or CT scans, and it could detect all types and all stages of lung cancer. This BARD1 lung cancer test could therefore be further developed as i) screening test for early detection of lung cancers in high-risk groups, and ii) diagnostic aid in complementing CT scan.