

US PATENT ISSUED PROTECTING BARD1-OVARIAN TEST

- **Key US Patent No 10,018,639 issued covering a kit for breast or ovarian cancer**
- **Patent family provides protection for BARD1-Ovarian test**

Perth, Australia, 12 July 2018: BARD1 Life Sciences Limited (ASX:BD1), a biotechnology company developing non-invasive cancer diagnostics, today announced that on 10th July 2018, the United States Patent and Trademark Office (USPTO) issued United States Patent number 10,018,639 in the name of BARD1 Life Sciences Limited titled “Kits for detecting breast or ovarian cancer in a body fluid sample and use thereof”.

The issued United States claims are directed to kits comprising peptides from BARD1 isoforms for detecting autoantibodies associated with breast or ovarian cancer. The patent application was filed on 23 September 2011 and is due to expire on 29 July 2032 with a possibility for further extension.

BARD1 LSL CEO, Dr Leeearne Hinch commented: “This is the first patent issued in this important patent family protecting our BARD1-Ovarian test, with the European case currently under examination. Additionally, a US continuation application has been filed to pursue further protection.”

The BARD1-Ovarian test is in development for early detection of ovarian cancer. Ovarian cancer is the leading cause of gynaecological cancer deaths and 11th most common cancer in women in the United States with about 22,240 new cases diagnosed and 14,070 deaths in 2018¹. Ovarian cancer is often diagnosed at a late-stage after the cancer has spread beyond the ovary, resulting in an overall 5-year survival rate of 47% in the US. Early detection of ovarian cancer when local rather than distant has the potential to save women’s lives by enabling earlier treatment and improving 5-year survival from 29% to 93%.

Additionally, this patent provides protection for a future breast cancer diagnostic test that the company may develop. Breast cancer is the most frequently diagnosed cancer in women in the United States, Europe and Australia and rapidly rising in Asia with 268,670 new cases diagnosed and 41,400 deaths in 2018 in the United States².

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ABOUT BARD1 LIFE SCIENCES LTD (BARD1 LSL)

BARD1 Life Sciences Ltd (ASX:BD1) is an Australian-based biotechnology company focused on developing and commercialising non-invasive diagnostic tests for early detection of cancer. BARD1’s proprietary technology platform is based on novel tumour markers with potential diagnostic and therapeutic applications across multiple cancers. The development pipeline includes two BARD1 autoantibody tests in development for early detection of lung and ovarian cancers, and a cancer vaccine project at research-stage for treatment of cancer. Additional diagnostic projects are being evaluated for prostate, breast and other cancers. BARD1 is committed to transforming the early detection and prevention of cancer to help improve patients’ lives. For more information on BARD1, see www.bard1.com.

¹ ACS. Ovarian Cancer Statistics. Available https://cancerstatisticscenter.cancer.org/?_ga=2.94221085.161224740.1531191000-2058916002.1531191000#!/cancer-site/Ovary, accessed on Jul 10, 2018.

²ACS. Breast Cancer Statistics. Available https://cancerstatisticscenter.cancer.org/?&_ga=2.148060401.717554454.1531298008-368837721.1469021392#!/, accessed on July 11, 2018

ABOUT THE BARD1 INTELLECTUAL PROPERTY PORTFOLIO

BARD1 has established a strong intellectual property position covering various BARD1 DNA and protein sequences, methods of diagnosis and treatment, and use in multiple cancers. The patent portfolio comprises 5 patent families with multiple granted and pending patents across key marketplaces including the US, Europe and Japan.

Figure 1: BARD1 Patent Status

Patent Family	Title	Granted	Pending	Expiry
PCT/FR01/02731	Truncated BARD1 protein and its diagnostic and therapeutic uses	US, JP		2021
PCT/IB2011/053635	BARD1 isoforms in lung and colorectal cancer and use thereof	US, JP, JP div, IL, CN, AU	US, CN (divisionals), EP, CA, BR, SG, HK	2031*
PCT/IB2011/054194	Kits for detecting breast or ovarian cancer in a body fluid sample and use thereof	US	US (divisional), EP	2031*
PCT/EP2014/073834	Lung Cancer Diagnosis		US, EP, CA, JP, IL, CN, AU, SG, KR, HK	2034*
EP14002398.7	Novel non-coding RNA, cancer target and compounds for cancer treatment		US	2035*

* Plus any extension of term in the US due to prosecution delay

ABOUT THE BARD1-OVARIAN TEST

BARD1-Ovarian is a blood test in development for early detection 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. BARD1-Ovarian could potentially be used as a screening test for early detection of ovarian cancer in high-risk asymptomatic women, for risk assessment of malignancy in women with pelvic masses, or to monitor ovarian cancer recurrence.

ABOUT OVARIAN CANCER

Ovarian cancer is the leading cause of gynaecological cancer deaths and seventh most common cancer in women worldwide, with around 239,000 new cases diagnosed and 152,000 deaths in 2012³. 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 47% 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 93%, a potential survival improvement of 3 times. There are currently no recommended screening tests for ovarian cancer in average-risk women without symptoms, identifying a clear unmet need for an accurate, reliable and affordable blood test for early detection 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 2020⁴.

³ 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

⁴ 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.