

## **BARD1 ACHIEVES hTERT REGISTRATION AND FIRST ORDER IN KOREA**

- **BARD1 gains Class II IVD device registration for hTERT from South Korea's Ministry of Food and Drug Safety**
- **BARD1's exclusive Korean distributor Mirax places first hTERT product order**

**Melbourne, Australia, 12 March 2021:** BARD1 Life Sciences Limited (ASX:BD1) (**BARD1** or the **Company**) is pleased to announce that it has gained Class II In-Vitro Diagnostic (IVD) medical device registration from South Korea's Ministry of Food and Drug Safety (MFDS) for the Company's hTERT test, which is used as an adjunct to urine cytology testing.

Mirax Corporation (Mirax) was appointed the Company's exclusive distributor for the hTERT product in the Republic of Korea on 21 December 2018. Mirax is the Korea License Holder (KLH) for hTERT and is required under the terms of the exclusive distribution agreement to place an agreed initial purchase order for hTERT within 2 days of receiving the MFDS registration.

All medical device manufacturers are required to comply with MFDS Quality Management System (QMS) regulations before their devices can be distributed in Korea. BARD1's subsidiary, Sienna Cancer Diagnostics, and its contract manufacturer were issued a Korea Good Manufacturing Practice (KGMP) certificate on 22 February 2021.

BARD1 has received the initial purchase order for A\$80,000 from Mirax and has notified its contract manufacturer to deliver the product as soon as possible.

BARD1 CEO Dr Leearne Hinch said: "Securing Korean registration and our first order from Mirax is the culmination of the BARD1 team's dedication and effort to expanding the geographical footprint for hTERT in Asia. We are excited to be entering the Korean market and are looking forward to working with the Mirax team to build a strong franchise for hTERT in this key Asian healthcare market."

The Korean medical device market is ranked as the ninth largest in the world valued at US\$6.8 billion in 2018. Urologic cancers, including bladder cancer, are a significant public health problem in the Republic of Korea. The incidence of urological cancer is rising globally and accounted for more than 8.0% of all cancers in Korea in 2011.<sup>1</sup> BARD1's hTERT test can assist pathologists to resolve indeterminate urine cytology to assist in bladder cancer diagnosis and improve patient outcomes.

Mirax CEO Sang-Ju Bae said: "Mirax believes there is a significant opportunity for hTERT to become a key product in the bladder cancer diagnostic market in Korea. We are confident that the Mirax / BARD1 partnership can position hTERT as a valuable tool for cytologists, pathologists and urologists in the fight against bladder cancer."

*Authorised by the Company Secretary, Tony Di Pietro.*

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<sup>1</sup> Jung KW, Won YJ, Kong HJ, Oh CM, Lee DH, Lee JS. Cancer statistics in Korea: incidence, mortality, survival, and prevalence in 2011. Cancer Res Treat. 2014;46:109-123.

### ABOUT BARD1 LIFE SCIENCES LTD

BARD1 Life Sciences Ltd (ASX:BD1) (**BARD1** or the **Company**) is a leading Australian diagnostics company with an innovative portfolio of diagnostic technologies and products. The Company is focused on developing and commercialising best-in-class diagnostic solutions for healthcare professionals and patients. The cancer diagnostics portfolio includes the commercialised hTERT test used as an adjunct to urine cytology testing and diagnostic tests in development for ovarian, breast, lung, prostate and pancreatic cancers. For more information on BARD1, see [www.bard1.com](http://www.bard1.com).

### ABOUT MIRAX CORPORATION

Mirax Corporation (Mirax) is a diagnostic medical device distributor headquartered in Seoul, South Korea. Since 2007, Mirax has been an icon of innovation and challenge in the Korean pathology diagnostic market. Through this sense of mission, Mirax is leading the automation of the Korean cytogenetics market and is challenging the next-generation liquid biopsy and pathology markets through innovative tools such as “hTERT”. Mirax is the exclusive Authorised Distributor for hTERT in the Republic of Korea and the Korea License Holder (KLH) for hTERT.

### ABOUT THE hTERT ASSAY

The hTERT test is an immunocytochemistry (ICC) assay that detects hTERT, a component of telomerase, which is increased in most human epithelial cancers. The test is used as an adjunct to urine cytology, assisting in the diagnosis of bladder cancer.

### FORWARD LOOKING STATEMENTS

This announcement contains certain ‘forward-looking statements’ within the meaning of the securities laws of applicable jurisdictions. Forward-looking statements can generally be identified by the use of forward-looking words such as ‘may,’ ‘should,’ ‘expect,’ ‘anticipate,’ ‘estimate,’ ‘scheduled’ or ‘continue’ or the negative version of them or comparable terminology. Any forecasts or other forward-looking statements contained in this announcement are subject to known and unknown risks and uncertainties and may involve significant elements of subjective judgment and assumptions as to future events which may or may not be correct. There are usually differences between forecast and actual results because events and actual circumstances frequently do not occur as forecast and these differences may be material. The Company does not give any representation, assurance or guarantee that the occurrence of the events expressed or implied in any forward-looking statements in this announcement will actually occur and you are cautioned not to place undue reliance on forward-looking statements.