BARD1 SIGNS OPTION AGREEMENT FOR TYPE 3C DIABETES TEST

- **Option Agreement signed with the University of Liverpool to license two novel protein markers for development and commercialisation of a novel type 3c diabetes (T3cDM) blood test**
- **T3cDM accounts for up to 10% of new-onset diabetes cases, but it is currently underdiagnosed and poorly managed**
- **BARD1 is also developing blood tests for early detection of pancreatic cancer and an accurate T3cDM test could enable better management of T3cDM and stratification of people at risk of developing pancreatic cancer**

Melbourne, Australia, 13 April 2021: BARD1 Life Sciences Limited (ASX:BD1) (**BARD1** or the **Company**) is pleased to announce that it has executed an exclusive two-year option agreement with the University of Liverpool (UK) to evaluate two novel protein biomarkers that, in preliminary testing, have been shown to accurately distinguish type 3c diabetes from type 2 diabetes (T2DM) in individuals newly diagnosed with diabetes.

The Option Agreement provides the Company with the option to license the intellectual property for development and commercialisation of a T3cDM test on commercial terms. BARD1 will pay a non-material upfront option fee and support patent costs incurred by the University of Liverpool.

There are around 22.9 million new cases of new-onset diabetes diagnosed globally[1], including 1.5 million cases in the US every year.[2] Type 3c diabetes (T3cDM; alternatively termed pancreatogenic diabetes) occurs in approximately 10% of all new-onset diabetes cases. T3cDM is primarily caused by inflammation of the pancreas (chronic pancreatitis, 80% cases), pancreatic cancer (10% cases), and cystic fibrosis. Currently, no test exists to identify T3cDM and it is most often misdiagnosed as T2DM and/or inappropriately managed. The correct diagnosis of T3cDM is not only important to ensure that the right treatment is delivered to patients to better manage the disease, but also because for certain individuals T3cDM is caused by underlying, undiagnosed pancreatic cancer. The identification of T3cDM in these individuals would provide a vital opportunity for earlier detection and treatment of pancreatic cancer.

BARD1's CSO Dr Peter French said: "In and of itself, a test for T3cDM could be an important diagnostic assay, as there would be a strong clinical case for using it to screen all individuals diagnosed with new-onset diabetes. Those individuals that test positive for type 3c diabetes could then be placed in an enhanced surveillance program and screened annually for pancreatic cancer using BARD1's specific pancreatic cancer tests currently in development. Clearly this approach could provide a significant improvement in outcomes for patients with both diseases."

The researchers at the University of Liverpool have reported that the combination of the two novel biomarkers (adiponectin and interleukin-1 receptor antagonist (IL-1Ra)) showed a high diagnostic potential for distinction of T3cDM from T2DM (AUC = 0.90), with optimal sensitivity and specificity of 83.7% and 90.0% respectively[3]. Professor Eithne Costello, a molecular biologist based at the University of Liverpool and one of the researchers leading the project, has since established the UK-Early Detection Initiative for Pancreatic Cancer (UK-EDI). UK-EDI are collecting relevant samples which will allow validation of the T3cDM markers in larger sample sizes.

Professor Costello said: "In the field of pancreatic cancer, there is currently widespread interest in finding ways to detect pancreatic cancer in individuals over 50 years of age who are newly diagnosed with diabetes. The UK-EDI study will collect pre-diagnostic samples and data from individuals who will

[1] 2019. International Diabetes Federation. IDF Diabetes Altas. 9th edition.
[2] https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf
[3] Oldfield L et al. Blood levels of adiponectin and IL-1Ra could facilitate earlier detection of PDAC by distinguishing individuals with type 3c diabetes from those with type 2 diabetes. *Pancreatology* 19:S3 DOI: 10.1016/j.pan.2019.05.004

subsequently receive a diagnosis of pancreatic cancer. This represents a significant step forward for the field of early pancreatic cancer detection and diagnosis."

These findings have key implications for future pancreatic cancer screening because certain individuals with T3cDM are at increased risk of developing pancreatic cancer. Known risk factors for pancreatic cancer include smoking, obesity, diabetes and chronic pancreatitis (the predominate cause of T3cDM). An accurate and reliable T3cDM test could be used to identify an at-risk population for a routine screening program for pancreatic cancer. There are no current screening tests available for pancreatic cancer that has a poor five-year survival rate of only 10%. BARD1 is investigating two novel approaches for screening pancreatic cancer using its SubB2M and EXO-NET technologies, with the aim of introducing a world-first screening test for this killer disease and important unmet need.

BARD1 CEO Dr Leearne Hinch said: "Currently no screening test is available for pancreatic cancer and even if there was, it would not be practical or cost-effective to screen the average-risk general population. BARD1's approach of developing a much-needed blood test for the detection of type 3c diabetes, which also provides a high-risk group for our screening test for pancreatic cancer, provides an ideal and clinically useful solution for both these global health problems. BARD1 continues to deliver on its mission to develop non-invasive diagnostic tests that make a real difference to patient health outcomes in critical areas of unmet medical need including Type 3c diabetes and pancreatic cancer."

Authorised by the Company Secretary, Tony Di Pietro.

- ENDS -

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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 based on its BARD1, SubB2M, Molecular NETs and hTERT platforms for healthcare professionals and patients. The cancer diagnostics portfolio includes the commercialised hTERT test used as an adjunct to urine cytology testing and development-stage tests for ovarian, breast, lung, prostate and pancreatic cancers. The Company is also commercialising its Molecular NETs platform for sample preparation and is launching its proprietary EXO-NET™ exosome capture tool for use in research for exosome-based diagnostics and therapeutics. For more information on BARD1 see www.bard1.com.

ABOUT THE UNIVERSITY OF LIVERPOOL

The University of Liverpool is one of the UK's leading research institutions and a centre of world-class teaching and learning. A member of the prestigious Russell Group of the UK's leading research universities, Liverpool has an annual turnover of £575 million. The University of Liverpool's mission is for advancement of learning and ennoblement of life. The University has been associated with nine Nobel Laureates and is recognised for its high-quality teaching and research. Research collaborations extend worldwide and address many of the grand challenges facing mankind today. The University is an inspirational centre of learning, which aims to support students as they become highly employable, creative, and culturally rich graduates, with the capacity to find employment that will enable them to be agents for change in a connected world. Visit www.liv.ac.uk or follow us on twitter at: http://www.twitter.com/livuninews.

ABOUT PANCREATIC CANCER

Pancreatic cancer was the 12th most common cancer and the 7th leading cause of cancer death worldwide, accounting for 495,773 new cases and 466,003 deaths in 2020.[4] In the USA, there were an estimated 57,600 people diagnosed with pancreatic cancer and 47,050 deaths in 2020.[5] Cancer Australia estimated there were 3,933 new cases diagnosed and 3,300 deaths from pancreatic cancer in Australia in 2020.[6] The 5-year survival rate for pancreatic cancer is only 10%. The poor prognosis for pancreatic cancer is largely due to the asymptomatic nature of early-stage pancreatic cancer and its late-stage diagnosis when the disease is locally advanced or metastatic (85% of cases) and can't be surgically removed. The median survival time for pancreatic cancer patients detected at late-stage is only 3 -14 months.[4] Early detection of pancreatic cancer when local (stage 1; 11% cases) increases 5-year survival to 39%, compared to late-stage detection of only to 3% when distant (stage III/IV, 52% cases).[7]

There are no accurate, reliable and specific screening tests to detect early-stage pancreatic cancer in people who have no symptoms. As a result, most people are diagnosed at a late stage when the cancer can't be surgically removed and/or has already spread from the pancreas. A blood test that could specifically detect asymptomatic premalignant or early malignant tumors and predict the response to treatment would greatly benefit pancreatic cancer patients by improving patient outcomes and survival.[8]

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.

[4] GLOBOCAN 2018 (IARC): Estimated Cancer Incidence, Mortality, and Prevalence Worldwide in 2018. https://gco.iarc.fr/today/home

[5] NIH. Cancer Stat Facts: Pancreatic Cancer. https://seer.cancer.gov/statfacts/html/pancreas.html

[6] Cancer Australia. Pancreatic cancer. https://www.canceraustralia.gov.au/affected-cancer/cancer-types/pancreatic-cancer/statistics

[7] ACS. Survival rates for Pancreatic Cancer. https://www.cancer.org/cancer/pancreatic-cancer/detection-diagnosis-staging/survival-rates.html

[8] Qi Z-H, Xu H-X, Zhang S-R, Xu J-Z, Li S, Gao H-L, Jin W, Wang W-Q, Wu C-T, Ni Q-X, Yu X-J, Liu L. The significance of liquid biopsy in pancreatic cancer. *J Cancer* 2018; 9(18): 3417-3426. doi: 10.7150/jca.24591