



ASX RELEASE

Sienna obtains exclusive worldwide licence to a unique cancer probe

- University of Adelaide and Griffith University researchers have engineered a unique protein that binds **specifically** to a sugar molecule only present in cancer cells
- The protein, called SubB2M, has the potential to detect cancer by using liquid biopsies, immunoassays, circulating tumor cell assays and PET imaging
- Sienna has the **exclusive worldwide** license to commercialise this technology
- Sienna will work with the University of Adelaide and Griffith University's Institute for Glycomics to develop SubB2M for a range of commercial cancer assays

Melbourne, Australia, 20 April 2020: [Sienna Cancer Diagnostics Ltd \("Sienna", ASX: SDX\)](#), a medical technology company developing and commercialising innovative cancer-related tests, has entered into an exclusive worldwide licence agreement with the University of Adelaide to develop and commercialise a unique cancer probe, SubB2M – a potential game-changer for detecting cancer, which is complementary to SIEN-NET™ and the BARD1 autoantibody assay for ovarian and breast cancer.

SubB2M binds to a unique sugar molecule only present in human cancers and can detect its presence in the serum of cancer patients.

In pilot clinical studies using surface plasmon resonance, SubB2M has detected cancers with 100% sensitivity and specificity for mid to late-stage cancers, and >95% specificity and 100% sensitivity for early-stage cancers. There is also evidence that the cancer-specific sugar is present in a wide range of solid human tumors and can be detected in serum using SubB2M.

Potential combination of SubB2M with BARD1's cancer tissue specific technology could provide the basis for a new highly sensitive and specific assay for the screening of serum and other body fluids from individuals at high risk of ovarian, breast and other cancers.

Sienna CEO, Mr Carl Stubbings, said: "We believe that this technology could radically improve how cancer is detected and diagnosed. It is recognised that the sugar molecule that SubB2M binds to is only present in people with cancer, having been engineered for this sole purpose in the Adelaide and Griffith universities' laboratories. The SubB2M protein is compatible with a wide range of cancer detection chemistries and assays, including with our SIEN-NETs to enhance circulating tumor cell binding and detection with no interference from non-cancer cells. In our opinion, SubB2M is superior to any other pan-cancer biomarker on the market. Furthermore, it has a broad range of applications beyond laboratory assays. It could also be used in *in vivo* imaging modalities, such as PET."

As part of the exclusive licence, Sienna will collaborate with the University of Adelaide and Griffith University's Institute for Glycomics to provide the data needed to commercialise cancer screening and diagnostic assays based on SubB2M.

The first stage will focus on developing a high throughput ELISA-based liquid biopsy assay for cancer screening and monitoring suitable for use in hospital pathology laboratories. It is anticipated that this will take 12-18 months to complete.



In parallel, Sienna will actively develop SubB2M for other applications, including a novel circulating tumor cell capture assay and a novel reagent for PET imaging in conjunction with industry partners. Appropriate industry partners for these applications have been identified and discussions are progressing well.

According to a 2019 report from Market Research Future, the global circulating tumor cell market was valued at USD 9.39 billion in 2017 and is expected to be worth USD 28.3 billion by 2023¹. SubB2M incorporated into SIEN-NETs should overcome the current limitations (very low sensitivity and time-consuming processing) of competitors' products. The global PET imaging market is significant with about 1.8 million tests for cancer performed each year in the US alone.

COMMENT FROM UNIVERSITY of ADELAIDE

"The University of Adelaide is very pleased to license this technology to Sienna Cancer Diagnostics, an Australian publicly listed company with the vision to realise the enormous potential of SubB2M," said Professor Anton Middelberg, Deputy Vice-Chancellor and Vice President (Research). "We are pleased to be working with Sienna to transform the global cancer diagnostics field and to address the unmet need for effective tools to support the early detection and stage progression of a range of cancers." The technology grew from research started more than 10 years ago by Adelaide researchers Professor Adrienne Paton and Professor James Paton, who said "We look forward to working with Sienna and our colleagues at Griffith's Institute for Glycomics to translate our research into improved outcomes for cancer patients. This is an outstanding example of transformational benefits to human health emanating from basic research in the university environment."

COMMENTS FROM GRIFFITH UNIVERSITY

Professor Michael Jennings, an NHMRC Principal Research Fellow and Deputy Director of the Institute for Glycomics at Griffith University said, "As a co-inventor of SubB2M, I am very excited that SubB2M is going to be developed for use as a screening and diagnostic tool by Sienna Cancer Diagnostics, an Australian company with a track record in developing and commercialising cancer diagnostic tests. My laboratory will work closely with Sienna to ensure that the SubB2M cancer tests are developed in a timely way to ensure optimal accuracy and efficacy on a high throughput platform."

Professor Mark von Itzstein AO, Director and Principal Research Leader of Griffith's Institute for Glycomics added, "From the laboratory bench to the patient's bedside, translational outcomes are the ultimate goal of the Institute for Glycomics. This is another wonderful example of how the Institute engages with industry to take our products to market, thus translating research into tangible benefits for the global community."

About liquid biopsy

Sienna Cancer Diagnostics research priorities include developing liquid biopsy technologies for non-invasive cancer detection.

"Liquid biopsy" is the term that describes diagnostic procedures performed on biofluids (blood, urine, plasma, serum, etc). The discovery of a wide variety of specific molecules, cells and particles that are strongly associated with cancers has shown the potential to change the practice from solid tumour biopsy to liquid biopsy. The advantages of a liquid biopsy approach over solid tumour biopsy include:

- Collecting a blood or other biofluid sample is minimally invasive and avoids the adverse clinical complications of tissue biopsies;

¹ <https://www.marketresearchfuture.com/reports/circulating-tumor-cell-market-1362>



- The use of fresh tumour-derived material eliminates the need for preservatives that can interfere with molecular analyses;
- The availability of the complete genomic and proteomic profile of the tumour because it is not dependent upon accurately localising and biopsying the tumour(s) within the tissue;
- Less invasive sampling, which allows repeatable and consistent assessment throughout the course of therapy.

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The release of this announcement was authorised by the Board of Sienna.

About Sienna Cancer Diagnostics

Sienna Cancer Diagnostics Ltd is an Australian medical technology company with operations in the United States, Europe, Asia, Latin America and Australia. Sienna's strengths lie in the identification, development and commercialisation of novel IVD technologies that satisfy an unmet clinical / market need. The company has taken its first product, an IVD test for the biomarker hTERT, from research, through development, manufacturing, product registration, and market launch through a growing network of distribution partners.

The company is focused on growing revenues from the existing product, increasing market access through new distribution partners, extending the applications for their hTERT test, and expanding their product offerings with the addition of new technologies into the product development pipeline.

Sienna's most recent technology acquisition was a unique technology for the capture and isolation of target analytes in liquid biopsy samples. The sample preparation technology, known as SIEN-NET™, can more accurately and rapidly prepare samples for the liquid biopsy testing of a range of clinically useful biomarkers, including exosomes, lipids, proteins, and other molecular targets of interest.

Forward Looking Statements

This announcement may contain forward-looking statements, which include all matters that are not historical facts. These forward-looking statements speak only as at the date of this announcement. These statements, by their nature, are subject to a number of known and unknown risks and uncertainties that could cause the actual results, performances and achievements to differ materially from any expected future results, performance or achievements expressed or implied by forward-looking statements. Without limitation, indications of, and guidance on, future earnings and financial position and performance are examples of forward-looking statements. No representation, warranty or assurance (express or implied) is given or made by Sienna that the forward-looking statements contained in this announcement are accurate, complete, reliable, or adequate or that they will be achieved or prove to be correct. Except for any statutory liability which cannot be excluded, each of Sienna, its related companies and their respective directors, employees and advisers expressly disclaim any responsibility for the accuracy or completeness of the forward-looking statements and exclude all liability whatsoever (including negligence) for any direct or indirect loss or damage which may be suffered by any person as a consequence of any information in this presentation or any error or omission therefrom.