



ASX RELEASE

Study Initiated at Royal Melbourne Hospital for Potential New Application of hTERT IVD Test

- Multiple sample types being sourced for a range of applications requiring internal R&D testing
- Ethics Committee approval received to commence a proof-of-concept study at the Royal Melbourne Hospital (RMH) investigating the utility of Sienna's hTERT IVD test in thyroid samples
- Thyroid cancer has a significant unmet clinical need

Melbourne, Australia, 30 August 2018: [Sienna Cancer Diagnostics Ltd, \(ASX:SDX\)](#) ("Sienna" or "The Company"), a medical technology company developing and commercialising innovative cancer-related tests, is pleased to announce it has entered a clinical proof-of-concept study agreement with the Royal Melbourne Hospital (RMH), and received ethics approval to investigate the potential use of its hTERT In-Vitro Diagnostic (IVD) test on Fine Needle Aspirate (FNA) samples from the thyroid gland.

The IVD test detects hTERT, a core component of telomerase which is upregulated in approximately 85 per cent of tissue-based cancers, giving the test potential application in a range of cancer types.

Sienna is actively investigating several candidate applications in which its hTERT IVD test may add clinical value. Thyroid cancer is just one of several potential follow-on applications, selected in part for the significant unmet clinical need in this area, with an estimated 1.5 million thyroid cytology tests performed worldwide every year.

Dr. Julie Miller, Specialist Endocrine Surgeon and Chair of the Thyroid Cancer Multidisciplinary Team, RMH, said of the study: "Thyroid nodules are very common, but usually harmless. A needle biopsy can usually tell doctors if a nodule is benign or cancerous. However, approximately 10% of thyroid needle biopsies are reported as indeterminate and carry a 20-30% chance of harboring cancer. Patients with this diagnosis typically undergo surgery to remove half the thyroid to make the diagnosis.

"Sienna's test may help resolve indeterminate needle biopsies limiting the number of patients that require surgical intervention. Our study will compare Sienna's hTERT test on thyroid needle biopsies with matched thyroid nodules after removal. The goal is to see whether the test is accurate enough to make a correct diagnosis, and spare patients with thyroid nodules from unnecessary surgery.

If successful, this technique will represent a major breakthrough in care for patients with indeterminate thyroid nodules, as patients with benign disease can avoid surgery altogether, while patients with cancer can have the correct operation the first time, rather than undergoing a two-stage procedure."



Sienna Cancer Diagnostics CEO Matthew Hoskin said, “We are looking forward to commencing this proof-of-concept study which, if successful, would allow us to follow on with a more extensive thyroid clinical study, while in parallel continuing to research other opportunities to expand our hTERT market. Developing additional applications for our unique hTERT IVD test is one of four growth drivers being pursued for our business.”

ENDS.

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About Sienna Cancer Diagnostics

Sienna Cancer Diagnostics Ltd. is an Australian medical technology company, with operations in the United States, Europe and Australia. Sienna’s strengths lie in identifying novel technologies then developing and commercialising them to satisfy an unmet clinical / market need. The Company has demonstrated the utility of its product with the help of its global clinical partners. Sienna’s primary platform is the detection of the biomarker telomerase, which is found in nearly all epithelial cancers, and was the subject of a Nobel Prize in 2009. Telomerase is well recognised for being used by 85% of cancers to enable immortal cell replication.

The FDA listing of Sienna’s first IVD in the United States, and CE marking / IVD registration in Europe and Australia, means the assay can be used for clinical diagnostic purposes by pathology laboratories. Clinical pathology laboratories in those regions may purchase the product for use as an in vitro diagnostic test for the presence of hTERT, a component of telomerase.

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.

