

ASX RELEASE

hTERT Clinical Study Initiated in Korea

- The study, led by Associate Professor of Pathology - Han Suk Ryu and his team from Seoul National University Hospital, will be a key market driver for product adoption
- Mirax Corporation (Mirax) will fund the first ever hTERT clinical utility study in Seoul, South Korea

Melbourne, Australia, 22 January 2020: [Sienna Cancer Diagnostics Ltd \(ASX:SDX\)](#) (“Sienna” or “the Company”), is pleased to announce the initiation of a South Korean clinical study utilising the Company’s novel adjunct urine cytology test, the hTERT test. The clinical study will involve a collaboration between Mirax, Sienna’s exclusive Korean distribution partner, and Seoul National University Hospital (SNUH).

The study, a Korean first, will provide further validation of the clinical utility of hTERT, investigating patients presenting with symptoms typically linked with bladder cancer, or being monitored for bladder cancer. The results will enable local pathologists and urologists to access data from a Korean population sample.

Mirax CEO, Mr Sang-Ju Bae said: “Bladder cancer is one of the top two cancers diagnosed in South Korea. The Republic of Korea presents a substantial market opportunity for both Sienna and Mirax with over 300,000 urine cytology tests believed to be performed annually. Sienna and Mirax have been progressing the hTERT product approval with South Korea’s regulatory body, the National Institute of Medical Device Safety Information (NIDS), which is a required step before commercial sales in this region can commence. Results from this study will be a key market driver and an important reference site for all Korean customers. We are extremely excited to be working with Professor Han Suk Ryu and SNUH. “

Sienna’s CEO and Managing Director, Carl Stubbings added: “The Sienna team, led by our Business Development Manager, Minesh Lalla, has made some important strides in our global expansion strategy over the past 12 months. The South Korean market represents an exciting and valuable opportunity for the Company. Sienna and Mirax have made great progress with the product approval process. With the SNUH study underway, Mirax is well placed for the launch of hTERT in mid-2020.”

ENDS.

For Further Information, please contact:

Carl Stubbings, CEO & Managing Director
Sienna Cancer Diagnostics Ltd
cstubbings@siennadiagnostics.com.au
+61 3 8288 2141

The release of this announcement was authorised by Tony Di Pietro, Company Secretary.



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.

