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## **New cancer detecting reagent available to US market, following FDA registration**

- *Sienna has registered its lead product, Anti-hTERT antibody (SCD-A7), with the US Food and Drug Administration (FDA)*
- *Using SCD-A7, US-based pathology laboratories will soon develop new urine tests, with initial applications expected in bladder cancer detection*
- *Advanced discussions underway with major US pathology laboratories, with first sales predicted in 2014*

**Sienna Cancer Diagnostics, a Melbourne-based biotechnology company focused on developing novel in vitro diagnostic (IVD) tests for cancer, has today announced the successful registration of its lead product, Anti-hTERT antibody (SCD-A7), with the US Food and Drug Administration (FDA).**

Under the registration, US-based pathology laboratories can develop their own diagnostic tests for cancer, utilising Sienna's reagent, SCD-A7 which is an antibody against telomerase, an established biomarker for cancer. Telomerase is an enzyme that elongates chromosome ends ("telomeres"), and can be found in 80-90% of human carcinomas. It was the focus of a Nobel Prize in 2009.

Given the established power of the telomerase biomarker in correlating with malignancy, global pathology labs are interested in accessing this new reagent to develop their own diagnostic tests. The registration of Sienna's SCD-A7 reagent makes this a possibility. Sienna is in advanced discussions with major US pathology companies, with first sales expected in the second half of 2014.

Sienna's Managing Director and CEO, Dr Kerry Hegarty said "US pathology labs will soon be the first in the world to be able to offer patients a urine test for bladder cancer developed using our product. Data from Sienna's in-house clinical studies indicated potential benefits of SCD-A7 over other current testing procedures. Those results, combined with the non-invasive nature of the test, represent an important innovation, both for clinicians and patients."

Cystoscopy is currently the industry standard for the diagnosis and monitoring of bladder cancer and can cost up to US\$2,000 per procedure. Simple, non-invasive urine tests using the Sienna reagent may assist in the early, cost effective detection of cancer, with an expected cost of less than US\$150 per test.

"There are few Australian companies that can boast that they have successfully completed an FDA registration. With more than 10 years of dedication to the development of ground breaking telomerase-based diagnostics, registration of this product with the FDA and imminent first sales mark major milestones for Sienna," she continued.

"The SCD-A7 manufacture and registration process has required us to comply with Good Manufacturing Practice, and the FDA's Quality Systems Regulations. We are now fully compliant, have completed our first manufacturing runs and are prepared to commence our sales and distribution program."

"The growing Sienna team and our valued US advisors deserve enormous praise for ensuring the expert management of the FDA registration. On behalf of the team, I'd also like to acknowledge the Australian Government for its Commercialisation Australia program which leveraged shareholder investment and expedited much of this work," Dr Hegarty said.

Bladder cancer is the fifth most common cancer in the United States, with more than 72,000 cases diagnosed in 2013. In 2014, the number of new cases of bladder cancer is expected to rise to over 74,500.

*Telomerase Diagnostics for Cancer*  
[www.siennadiagnostics.com.au](http://www.siennadiagnostics.com.au)

In addition to commercial progress in the US, Sienna is in commercial and clinical discussions in Australia and Europe. Longer term distribution plans include South East Asia, Canada and South America. The FDA product registration represents the launching point from which Sienna's telomerase platform may expand to several regions and different oncology indications.

**For more information, please contact:**

Dr Kerry Hegarty  
Sienna Cancer Diagnostics, Managing Director  
T: (03) 9347 0622  
E: [news@siennadiagnostics.com.au](mailto:news@siennadiagnostics.com.au)

Tahlia Weston  
Buchan Consulting  
(03) 8866 1203  
[tweston@buchanwe.com.au](mailto:tweston@buchanwe.com.au)

**About Sienna Cancer Diagnostics**

Established in 2002, Sienna Cancer Diagnostics Limited is an unlisted public biotechnology company, specialising in the development of novel reagents and diagnostic tests for cancer, using telomerase, a powerful biomarker. Telomerase is an enzyme that elongates chromosome ends ("telomeres") and can be found in 80-90% of human carcinomas and circulating cancer cells. The telomerase platform drives Sienna's pipeline and underpins the establishment of key partnering opportunities worldwide.

**About anti-hTERT antibody (SCD-A7)**

Sienna's anti-hTERT antibody (SCD-A7) which can be used in lab developed tests to detect telomerase has the potential to become a key component in cancer diagnostic tests. Registration of SCD-A7 with the US Food and Drug Administration (FDA) as an Analyte Specific Reagent (ASR) follows two key pieces of work. The first is the successful manufacture of cGMP product, a rigorous process to assure the strength and quality of products. The second is compliance with the FDA's Quality Systems Regulations, under the process and production control system 21 CFR 820, which allows Sienna to serve as the exclusive Legal Manufacturer of the novel reagent. Following FDA registration, US-based pathology companies can use SCD-A7 as part of a urine-based in vitro diagnostic (IVD) test to detect bladder cancer. Sienna predicts first sales of the product in the last half of 2014.

**About Telomerase and Bladder Cancer**

Telomerase is a naturally-occurring enzyme which is expressed in some replicating human cells and malignant tumours, including bladder cancer. It is widely regarded as having potential in both therapeutic and diagnostic applications. In 2009, the Nobel Prize in Physiology / Medicine was awarded for the discovery of this powerful protein to three co-workers, including Australian Elizabeth Blackburn. Unlike many potential cancer biomarkers in development, telomerase is well-established in the scientific literature as associated with ~90% of human cancers, signifying its key role in cancer development.

Bladder cancer is the fifth most common cancer in the USA, and the first in terms of total medical care cost per patient due to its propensity to re-occur after diathermy or resection of lesions from the bladder wall. There is a higher occurrence of bladder cancer in eastern Europe associated with toxicity and smoking. Over 70,000 individuals are diagnosed with bladder cancer annually in the USA and more than 530,000 people in the USA live with a history of bladder cancer, thus requiring regular diagnostic monitoring. It is estimated that more than one million cytology tests are conducted annually in the USA for initial diagnosis and ongoing monitoring of bladder cancer patients. The gold-standard (invasive) test for diagnosis (called a cystoscopy) can cost up to \$US2,000 per procedure. Simple, non-invasive urine tests using the Sienna reagent are expected to assist in the early detection of cancer, be cost effective at less than US \$150 per test, and be in line with rapidly evolving changes in global health care policies.

**Forward Looking Statements**

*This document contains statements relating to Sienna's future revenue stream and product development that may constitute forward-looking statements. These statements may be identified by words such as "potentially", "will", "looking to", "vision", "goal", "could be", "intends", "expected", "estimates", "ideally" or words of similar meaning. Sienna may also make forward-looking statements in other press releases or documentation including both written and oral statements. Any such statements are based on Sienna's current expectations and are, therefore, subject to known and unknown risks and uncertainties. A variety of factors, many of which are beyond Sienna's control, affect Sienna's performance, achievements, results and product development and could cause the actual performance, achievements, results and product development of Sienna to be materially different from any future performance, achievements, results and product development that may be expressed or implied by any such forward-looking statements. No representation or warranty, express or implied, is made by Sienna that any forward-looking statements contained in this document will be achieved as actual results and future events could differ materially from those anticipated in such statements. Accordingly, readers should not place undue reliance on any statements in this document which may constitute forward-looking statements.*