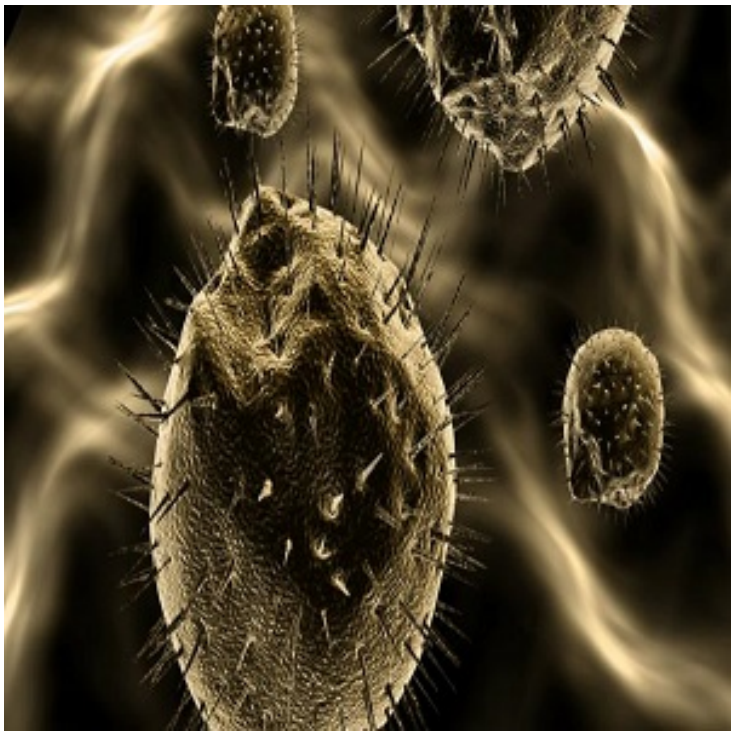
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Aussie firm gets FDA nod to supply cancer antibody in US labs

29 May 2014 | Regulatory | By BioSpectrum Bureau



Singapore: Sienna Cancer Diagnostics, Melbourne-based biotechnology company focused on developing novel in-vitro diagnostic (IVD) tests for cancer, has got USFDA approval for application of its Anti-hTERT antibody (SCD-A7) in US pathology labs.

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, and can be found in 80-90 percent of human carcinomas. It was the focus of a Nobel Prize in 2009.

Dr Kerry Hegarty, MD, Sienna, 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.