CXBLADDER MONITOR PAPER TO BE PUBLISHED IN PRESTIGIOUS JOURNAL OF UROLOGY

Cxbladder Monitor shows superior performance in ruling out recurrence of bladder cancer

The prestigious American Journal of Urology has accepted for publication a paper confirming the superior performance of Pacific Edge’s Cxbladder Monitor test for the surveillance of bladder cancer recurrence, offering patients with bladder cancer the potential utility of avoiding or deferring some cystoscopies.

Titled “Performance Characteristics of a Multigene Urine Biomarker Test for Monitoring for Recurrent Urothelial Carcinoma in a Multicenter Study”, the paper validated the performance of Cxbladder Monitor as a high-sensitivity urine test for ruling out the presence of urothelial carcinoma (bladder cancer) during routine surveillance for recurrence of the disease.

Specifically, the paper found that the Cxbladder Monitor test demonstrated high test sensitivity (93%) and high negative predictive value (97%) which provide physicians with actionable results and a high level of certainty when looking to rule out bladder cancer recurrence. Using Cxbladder Monitor as a confirmatory negative adjunct to cystoscopy, or to justify postponing future cystoscopic investigations in select patients offers significant clinical utility.

The paper noted that the high performance of Cxbladder Monitor was independent of patient demographics, tumour stage and grade, and regardless of whether or not patients had undergone BCG treatment.

The paper concluded that Cxbladder Monitor provides clinicians with a greater degree of certainty when monitoring for recurrent bladder cancer, or as a direct rule-out test for patients identified as being at low risk for recurrent disease, thereby avoiding cystoscopies in patients with a negative Cxbladder Monitor result.

Chief Executive Officer of Pacific Edge, David Darling, commented: “Cxbladder Monitor provides an opportunity to enhance the standard of care for bladder cancer patients, making monitoring of this disease more effective and importantly for the patient, less invasive. The test shows a high level of performance and is particularly robust in monitoring patients undergoing surveillance. The addition of Cxbladder Monitor to our portfolio supports our strategy to provide a ‘one stop shop’ of bladder cancer products designed to meet different clinical needs.”

The peer reviewed scientific paper will shortly be available online at the Journal Of Urology website and will be published in a subsequent print edition of the Journal, which is circulated to over 22,000 members of the American Urological Association, with the product launch process currently underway in the USA.

Cxbladder Monitor was launched in New Zealand in December 2015, and was recently adopted by Auckland’s Waitemata District Health Board for patients undergoing routine surveillance for bladder cancer recurrence. It is Pacific Edge’s third cancer diagnostic test, as the company continues to build its suite of simple, accurate and non-invasive cancer diagnostic tests. Cxbladder Triage helps to rule out cancer in patients with haematuria (blood in the urine) who have a low probability of having bladder cancer; Cxbladder Detect is used specifically to detect bladder cancer; and Cxbladder Monitor provides urologists who are evaluating patients for the recurrence of the disease, with greater certainty of their clinical evaluations, and patients with a non-invasive way to monitor their disease.

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OVERVIEW www.pacificedge.co.nz www.pacificedgedx.com
Pacific Edge Limited (NZX: PEB) is a New Zealand publicly listed, cancer diagnostic company specialising in the discovery and commercialisation of diagnostic and prognostic tests for better detection and management of cancer. The company is developing and commercialising its range of Cxbladder bladder cancer tests globally through its wholly owned central laboratories in New Zealand and the USA. The company’s products have been tested and validated in international multi-centre clinical studies.

Pacific Edge has three proprietary, novel, accurate, molecular diagnostic products in-market providing actionable results, and better detection and management of urothelial cancer. Cxbladder Detect and Cxbladder Triage are available through the company’s dedicated CLIA certified laboratories for customers in New Zealand, Australia and the USA. Cxbladder Monitor launched in New Zealand in December 2015 and is anticipated being available in the US in 2016.

ABOUT Cxbladder Triage www.cxbladder.com
Cxbladder Triage combines the power of the genomic biomarkers with additional phenotypic and clinical risk factors to accurately identify patients with haematuria who have a low probability of bladder cancer and may not require a more extensive urological evaluation. Cxbladder Triage is a tool for use by clinicians and physicians in primary evaluation of patients with hematuria and is intended to reduce the need for an expensive and invasive work-up in patients who have a low probability of having urothelial carcinoma.

ABOUT Cxbladder Detect www.cxbladder.com
Cxbladder Detect enables the non-invasive detection of bladder and other urinary tract cancers from a small volume of a patients’ urine. Cxbladder Detect was launched in 2013 in the USA and is commercially available in New Zealand, Australia and the USA as a Laboratory Developed Test (LDT) from the company’s CLIA certified laboratories. Cxbladder Detect provides physicians and clinicians with a quick, cost effective and accurate measure of the presence of the cancer as an effective adjunct to cystoscopy.

ABOUT Cxbladder Monitor www.cxbladder.com
Cxbladder Monitor, the third test in the Cxbladder portfolio for urologists, is a proprietary, non-invasive, molecular diagnostic test that combines genomic biomarkers measured from a small quantity of a patient’s urine, with patient specific clinical factors to better monitor bladder cancer patients for recurrence. Bladder cancer has a recurrence rate of 50-80% and requires lifelong surveillance. Cxbladder Monitor accurately identifies patients with a prior history of urothelial cancer (UC) whose Cxbladder Monitor score shows that they have a low probability of recurrent urothelial carcinoma. Cxbladder Monitor is designed to be used as the preferred adjunct test to cystoscopy in the management of patients for ongoing evaluation of recurrent bladder cancer.

Refer to www.cxbladder.com for more information.