

CXBLADDER MONITOR SIGNIFICANTLY OUTPERFORMS ALL FDA APPROVED URINE TESTS FOR BLADDER CANCER

Cxbladder Monitor clinical paper accepted for publication in Journal of Urologic Oncology

The prestigious international journal Urological Oncology, has accepted for publication a scientific and clinical paper validating the superior performance of Pacific Edge's Cxbladder Monitor test for the surveillance of patients who are being managed following treatment for bladder cancer. This follows the recently announced acceptance for publication of the Cxbladder Monitor validation study in the American Journal of Urology.

Titled "Clinical Comparison of Non-invasive Urine Tests for Ruling Out Recurrent Urothelial Carcinoma of the Bladder", the paper compared the performance of the Cxbladder Monitor test to other commonly available urine markers and cytology for surveillance of patients with urothelial carcinoma (bladder cancer).

Specifically, the paper, based on a Clinical Research Organisation (CRO) managed study with data from over 1100 USA patient samples, found that the Cxbladder Monitor test significantly outperforms current Food and Drug Administration (FDA) approved urine-based monitoring tests, including cytology and UroVysion® FISH, in a large representative population undergoing surveillance for recurrent urothelial carcinoma¹. This supports using Cxbladder Monitor as a confirmatory negative adjunct to cystoscopy or to justify postponing cystoscopic investigations in select patients. The paper concludes that this performance signals a step change in clinical utility for urologists managing patients in a surveillance regime for recurrence of the disease.

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

The paper noted that currently the major limitations in the other existing urine tests used for the monitoring of patients to date has been inadequate sensitivity, particularly for early stage and low grade tumours that account for a significant proportion of recurrences. Cxbladder Monitor combines high sensitivity and high Negative Predictive Value (NPV), both of which are essential for an effective rule-out test, outperforming all comparator tests irrespective of the patient's age and gender, recurrent tumour size, stage and grade, or duration post-treatment with adjuvant BCG.

Chief Executive Officer of Pacific Edge, David Darling, commented: "Cxbladder Monitor has been highlighted in this journal for its outstanding performance in the monitoring of bladder cancer. Overall, it offers an 'increase in clinical utility warranting consideration for inclusion in the guidelines'. As stated in the paper Cxbladder Monitor 'significantly out performs current FDA approved urine tests used in the management of bladder cancer'.

¹ **Study Results:** The sensitivity of Cxbladder Monitor (0.91) significantly outperformed cytology (0.20), NMP22® enzyme-linked immunosorbent assay (0.26) and NMP22® BladderChek® (0.11). The negative predictive value of Cxbladder Monitor was also superior at 0.96 compared with cytology (0.87), NMP22® enzyme-linked immunosorbent assay (0.87), NMP22® BladderChek® (0.86). UroVysion® FISH also had inferior sensitivity (0.36) and negative predictive value (0.92) compared to Cxbladder Monitor. All false negative results (n=14) observed using Cxbladder Monitor were also negative for cytology, NMP22® enzyme-linked immunosorbent assay and NMP22® BladderChek®, and UroVysion® FISH.

“Cxbladder Monitor provides an opportunity to enhance the standard of care for bladder cancer patients, making surveillance of patients with this disease and the monitoring for the recurrence of the disease, more effective and importantly for the patient, less invasive. The paper supports our strategy to provide a ‘one stop shop’ of high performance bladder cancer products designed to meet targeted clinical needs.”

“Cxbladder Monitor has recently been adopted in New Zealand by the Waitemata District Health Board and added to their standard of care for evaluation of low risk patients who are presenting to the clinic for evaluation for the recurrence of the disease. For these low risk patients Cxbladder has replaced cystoscopy.”

The peer reviewed paper will be published in the online edition of Urological Oncology, which provides practical, timely, and relevant clinical and basic science information to physicians and researchers practicing urology worldwide. The print copy publication will be available on the next edition of the Journal.

Cxbladder Monitor, sensitivity of 0.93 and Negative Predictive Value (NPV) 0.97, was launched in New Zealand in December 2015, and late 2016 in the USA following acceptance for publication of the clinical validation study. It is the third of Pacific Edge’s cancer diagnostic tests, as the company continues to build its ‘one stop shop’ of accurate and non-invasive cancer diagnostic tests. Cxbladder Triage helps to rule out cancer in patients who have a low probability of having urothelial 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.

For more information contact:

David Darling
Chief Executive Officer
Pacific Edge Ltd
P: +64 (3) 479 5800

OVERVIEW www.pacifiedge.co.nz www.pacifiedgedx.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 haematuria 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

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 life-long 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.