SIGNIFICANT INCREASE IN CLINICAL UTILITY FROM USE OF CXBLADDER

An international study demonstrates compelling changes in urologists' clinical decisions, with use of Cxbladder Triage and Cxbladder Detect leading to fewer total tests and less invasive procedures, implying a reduction in healthcare costs and an improved experience and outcome for patients.

Cancer diagnostics company, Pacific Edge Limited (NZX: PEB), is pleased to announce the approval for publication of an international study showing the significant increase in clinical utility derived from the inclusion of both Cxbladder Triage and Cxbladder Detect in the urologists' diagnostic procedures.

The study demonstrated the compelling changes to clinical decision making by urologists when provided with Cxbladder results for patients presenting with haematuria (blood in the urine) for detection of the presence of urothelial cancer (bladder cancer).

Both Cxbladder Triage and Cxbladder Detect were evaluated in the clinical utility study which involved 396 clinician by patient interactions and totalled 792 separate clinical decisions. Urologists first recommended a selection of tests and procedures for patients based on referral data; they were then given the data from the Cxbladder Triage and Detect tests and their initial recommendations were reviewed and amended.

All of the urologists changed their diagnostic recommendations once they assessed the Cxbladder results ranging from 1 to 100% of the patient cases. This led to a reduction of 25% in the total number of diagnostic procedures for patients, including a 31% reduction in invasive tests, following inclusion of both the Triage and Detect results for those patients.

The study concludes that the use of Cxbladder provides a significant increase in clinical utility by focusing the use of specific diagnostic procedures to appropriate patients, resulting in a reduction of both the total number of procedures and the number of invasive procedures used in clinical management of patients who present to the clinic with haematuria for evaluation of urothelial cancer. This therefore improves both the diagnostic experience and outcomes for clinicians and patients alike.

CEO of Pacific Edge, David Darling, said: "These findings are of material importance to all clinicians involved in the diagnosis of bladder cancer, and are of particular relevance to payers and funders of healthcare, such as the Centres for Medicare and Medicaid. Cxbladder provides solutions that not only improve the patients' experience and outcome, but also enable the reallocation of appropriate diagnostic procedures, particularly expensive and invasive procedures. There is also the potential for a significant reduction in the total cost to healthcare payers by reducing the number of diagnostics procedures required.

"Changing clinical behaviour is not simple, however, in this study, overwhelmingly, clinicians made significant changes and reallocations of their diagnostic procedures when provided with the Cxbladder results.

"Clinical and scientific papers such as these are an important part of our commercial strategy and essential in validating our products with major healthcare providers and funders in the United States, which is our primary focus."

This is the first time the clinical utility of both Cxbladder Triage and Cxbladder Detect combined, has been evaluated. The paper has been approved for publication in the *Advances in Therapy* Journal, an international, peer reviewed, journal dedicated to the publication of high-quality clinical, observational, real-world, and health outcomes research around the discovery, development, and use of therapeutics and interventions (including devices) across all therapeutic areas.

The publication of this study follows on from two other recently published studies announced by Pacific Edge. In December 2016, a study on Cxbladder Monitor was accepted for publication in the *Journal of Urology*, followed by acceptance of a second clinical paper on Cxbladder Monitor being accepted by the *Urological Oncology* journal in March 2017. Both of these studies confirmed the superior performance of Cxbladder Monitor for the surveillance of bladder cancer recurrence with the second of these papers showing that Cxbladder Monitor outperformed all compared, FDA approved urine tests.

Pacific Edge is the only company in the word to have a suite of four molecular diagnostic tests for the detection, management and monitoring of bladder cancer. 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. Cxbladder Resolve is the latest product to be launched, providing urologists with a frontline tool for identifying patients with high grade and late stage 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 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.