Company Announcement
10th May 2022

LOBSTER CLINICAL TRIAL TO ADVANCE CXBLADDER MONITOR AS A STANDARD OF CARE

*Pacific Edge's **Longitudinal Bladder Cancer Study for Tumor Recurrence** (LOBSTER) study is a multi-centre observational study to advance the inclusion of the Cxbladder Monitor into global urothelial cancer guidelines as a standard of care in bladder cancer surveillance.*

DUNEDIN, New Zealand -- Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) today announces it is advancing its clinical evidence generation program with LOBSTER – a clinical study focused on demonstrating the clinical utility of Cxbladder Monitor for surveillance of recurrent urothelial cancer against the current American Urological Association (AUA) standard of care targeting existing guidelines language for greater inclusion of Cxbladder.

Pacific Edge has contracted two sites, has initiated one site to date, and expects to enrol the first patient in LOBSTER this quarter.

Cxbladder Monitor is a urine-based gene expression biomarker test for the surveillance of recurrent disease in bladder cancer patients. International peer reviewed publications[1],[2],[3] have already shown the test's success in identifying those patients with a prior history of urothelial cancer that have a low probability of disease recurrence.

By identifying these patients, healthcare providers are able to introduce a significant change in clinical practice, enabling all patients who test negative, to safely undergo cystoscopies at longer intervals than submitting to a cystoscopy at every visit, the AUA's current standard of care.

This outcome significantly reduces the burden of invasive and expensive cystoscopic evaluations; spares patients the potential risks, discomfort and anxiety from cystoscopy, without compromising detection rates. It can also free up resources to be focused on patients most in need and facilitate compliance with cancer surveillance and management regimes.

Pacific Edge Chief Executive Dr Peter Meintjes said: "LOBSTER builds on previous validation and clinical utility studies showing that Cxbladder can be incorporated into a surveillance strategy to safely reduce the frequency of cystoscopy for intermediate and high-risk patients."

Pacific Edge's multi-centre observational study is recruiting an estimated 426 patients from the US Veterans Administration, America's largest integrated health care system, US academic centres as well as patients from research collaboration sites in Australia.

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[1] 1. Kavalieris L, O'Sullivan PJ, Frampton C, et al. Performance Characteristics of a Multigene Urine Biomarker Test for Monitoring for Recurrent Urothelial Carcinoma in a Multicentre Study. J Urol 2017;197:6,1419-1426.
[2] Lotan Y, O'Sullivan P, Raman JD, Shariat SF, Kavalieris L, Frampton C, et al. Clinical comparison of non-invasive urine tests for ruling out recurrent urothelial carcinoma. Urologic Oncology: Seminars and Original Investigations. Elsevier; 2017;1–8.
[3] Koya M, Osborne S, Chemasle C, Porten S, Schuckman A, Kennedy-Smith A. An evaluation of the real-world use and clinical utility of the Cxbladder Monitor assay in the follow-up of patients previously treated for bladder cancer. BMC Urology. 2020; 20:12.

Patients enrolled in the study will have been previously diagnosed with urothelial cancer and categorised as either intermediate or high-risk for urothelial cancer recurrence under the AUA 2020 Non-muscle Invasive Bladder Cancer (NMIBC) guidelines.

Over four visits during a 12-24-month surveillance period, patients will provide a urine sample, which will be used for Cxbladder Monitor testing and central urine cytology.

The study will also collect tumour tissue from the first (primary) tumour and also from the most recent recurrence, if any, in order to genotype each tumour using DNA markers indicative of an elevated risk of urothelial cancer.

Patient records will be reviewed up to four years after the final urine sample in order to check clinical outcome when Cxbladder indicates high probability of bladder cancer when cystoscopy was negative. Consistent with the gold standard of evidence generation in double-blinded studies, neither the patients nor the clinicians will be informed of the outcome of the Cxbladder Monitor tests and all patients will remain on standard of care. The study is due to deliver its first results in 2024.

Dr Meintjes said: “LOBSTER is an important component of Pacific Edge’s ongoing commitment to demonstrating the clinical utility of Cxbladder in pursuit of further inclusion into global standards of urothelial cancer diagnosis and management.

“Cxbladder already has substantial adoption for detection and surveillance of urothelial cancer with more than 2,000 urologists using the test in the workup of more than 80,000 patients.”

“Our urine based Cxbladder tests are non-invasive and allow for sample collection in the privacy of a patient’s home with our patient in-home sampling system and therefore can help to overcome entrenched patient non-compliance with management and surveillance regimes.”

“Pacific Edge is convinced about the utility of its tests in delivering improved patient outcomes and is looking forward to reporting the progress of the study,” Dr Meintjes said.

For more information:

Dr Peter Meintjes
Chief Executive Officer
Pacific Edge Limited
P: 022 032 1263

Richard Inder
The Project
P: +64 21 645 643

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OVERVIEW www.pacificedge.co.nz www.pacificedgedx.com

Pacific Edge Limited (NZX/ ASX: PEB) is a global cancer diagnostics company leading the way in the development and commercialisation of bladder cancer diagnostic and prognostic tests for patients presenting with haematuria or surveillance of recurrent disease. Headquartered in Dunedin, New Zealand, the company provides its suite of Cxbladder tests globally through its wholly owned, and CLIA certified, laboratories in New Zealand and the USA.

About Cxbladder www.cxbladder.com

Cxbladder is a non-invasive genomic urine test optimized for the detection and management of bladder cancer. The Cxbladder evidence portfolio developed over the past 14 years includes more than 20 peer reviewed publications for primary detection, surveillance, adjudication of atypical urine cytology and equivocal cystoscopy. Cxbladder is the focal point of numerous ongoing and planned clinical studies to generate an ever-increasing body of clinical utility evidence supporting adoption and use in the clinic to improve patient health outcomes. Cxbladder is reimbursed by CMS and has been trusted by over 2,000 US urologists in the diagnosis and management of more than 80,000 patients, including the option for in-home sample collection. In New Zealand, Cxbladder is accessible to 70% of the population via public healthcare and all residents have the option of buying the test online.