Company Announcement
13 December 2022

ENHANCED CXBLADDER TESTS DELIVER IMPROVED DIAGNOSTIC PERFORMANCE

DUNEDIN, New Zealand – Pacific Edge (NZX, ASX PEB) today announces the acceptance for publication of new clinical evidence that shows significant improvements in the performance of its genomic diagnostic Cxbladder tests. These performance improvements were achieved by the addition of DNA biomarkers to Cxbladder Triage (CxbT) and Cxbladder Detect (CxbD), Pacific Edge's products for hematuria evaluation.

Pacific Edge also announces its intent to focus further clinical evidence generation efforts on the enhanced test, Cxbladder Detect$^+$ (CxbD$^+$), extending Pacific Edge's first mover advantage in providing best-in-class diagnostic tools for the detection and management of bladder cancer.

The results of the study are to be published in the prestigious American Urological Association (AUA) Journal of Urology. The study enrolled 804 patients (344 from the US and 460 from Singapore), and the data shows an improvement in all performance characteristics over the existing versions of CxbT and CxbD. Notably, CxbD$^+$ delivered Sensitivity of 97% (+23% compared with CxbD), Specificity of 90% (+8%), Negative Predictive Value of 99.7% (+2.5%), Positive Predictive Value of 44% (+19%) and Rule-out Rate of 83% (+5%).

Pacific Edge Chief Executive Dr Peter Meintjes says, "By adding DNA biomarkers, we have developed Cxbladder Detect$^+$, a single product for hematuria evaluation that can assist clinicians to safely and reliably rule in or rule out the presence of bladder cancer for any hematuria patient at any point in the patient care pathway."

CxbD$^+$ was developed including a Southeast Asian patient population, further strengthening the evidence for genomic biomarker tests in genetically diverse populations, and specifically validating Cxbladder for use in Southeast Asia.

Pacific Edge expects no impact to revenue from existing products - commercial Triage and Detect customers will only be transitioned to CxbD$^+$ after reimbursement is established.

Dr Meintjes says, "Detect$^+$ will require its own coding, coverage and pricing decisions to ultimately establish reimbursement however, given the increased performance it could potentially receive a higher price. Our existing clinical evidence generation program, specifically the company's DRIVE study[1], will generate clinical validity evidence for Detect$^+$. We will announce additional clinical validity and clinical utility studies designed specifically for Detect$^+$ as those plans mature."

The company will continue to explore whether DNA markers will have a similar impact on the performance of Cxbladder Monitor for recurrence of disease.

The publication, *'Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification*', will be made available on Pacific Edge's website as soon as it is available.

Released for and on behalf of Pacific Edge by Grant Gibson Chief Financial Officer.

[1] Details of the DRIVE clinical study are available in the company's Annual Report for the year to the end of March 2022.

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Pacific Edge Limited (NZX/ ASX: PEB) is a global cancer diagnostics company leading the way in the development and commercialization of bladder cancer diagnostic and prognostic tests for patients presenting with hematuria 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.