Company Announcement
12 February 2020

REAL WORLD EVIDENCE HIGHLIGHTS CLINICAL UTILITY OF CXBLADDER

Publication Of Real World Clinical Evidence Highlights Significant Clinical Utility From Cxbladder Adoption

Cancer diagnostics company, Pacific Edge Limited (PEB: NZX) has today announced the publication of further real world evidence of significant gains in clinical utility from the commercial adoption of Cxbladder Monitor (CxbM) by several of New Zealand's public healthcare providers.

CxbM was integrated into local practice guidelines by healthcare providers to monitor patients for recurrence of urothelial cancer (UC), and 'rule out' those patients with no presence of the disease. By identifying these patients, these healthcare providers were able to introduce a significant change in clinical practice, enabling all patients, who test negative, to safely undergo cystoscopy at a longer interval than is otherwise the case.

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; and allows resources to be focused on patients most in need.

Independent, peer reviewed, published papers such as this provide the clinical evidence that drives successful inclusion in guidelines and positive coverage policy decisions for reimbursement. Clinical evidence is also a critical component for consideration in a Local Coverage Determination (LCD), which would enable reimbursement for Cxbladder from the Centers for Medicare and Medicaid (CMS) in the USA.

CEO of Pacific Edge, David Darling, commented: "Further published evidence of Cxbladder's clinical utility is the conclusive milestone required by our Medicare Administrative Contractor (Novitas) for Cxbladder's inclusion in the LCD. Clinical evidence is the driver behind successful reimbursement coverage decisions and this latest publication adds substantive new clinical utility evidence to the company's portfolio."

"The adoption of CxbM into the standard care by a number of New Zealand's public health care providers highlights the impact of Cxbladder's clinical utility. A successful inclusion in the LCD would complete the three milestones required for reimbursement of our Cxbladder tests by the USA's public healthcare payer, CMS."

Clinical Publication Overview and Summary:

CxbM has been integrated into the standard of care by healthcare providers to monitor patients for recurrence of UC, and 'rule out' those patients who do not have UC. The audit evaluated 309 patients, classified as either low or high risk by urologists, over a 35-month period by three of New Zealand's public healthcare providers.

The results from this independent clinical audit demonstrates the real world clinical utility of CxbM as a rule-out test for both low and high-risk patients undergoing surveillance for recurrent UC.

Key results and conclusions:

- CxbM successfully ruled out 78% of patients who did not have disease from all patients classified as either low-risk or high-risk by physician.

- The integration of CxbM into local practice guidelines accurately identified a high proportion of patients (77.8%) who were safely managed by only one cystoscopy every two years (compared to the current regimen of several cystoscopies over this period).
- Including CxbM in the protocol for patient surveillance provided clinical utility by reducing the average number of annual cystoscopies by approximately 39%, thereby sparing patients the potential discomfort and anxiety from cystoscopy, without compromising detection rates.
- CxbM missed no high grade tumours or failed to identify high-risk patients and the rate of pathology-confirmed UC recurrence was 16.2-fold lower in CxbM-negative than CxbM-positive patients.
- Previous studies have shown that CxbM has high sensitivity and NPV[1], and the current audit further demonstrates that CxbM provides tangible clinical utility when used as a rule-out test to identify patients at low risk of recurrence who do not need a cystoscopy and to identify those patients at higher risk who would benefit from cystoscopy.
- Based on these published data, several of New Zealand's public healthcare providers have integrated CxbM into their routine clinical surveillance of patients for recurrence of bladder cancer. The new clinical practice alternates the use of CxbM and cystoscopy during regular surveillance of low-risk patients.

Benefits of using CxbM

Bladder cancer carried the highest per-lifetime, per-patient cost of any cancer, with more than 60% of the total cost attributable to surveillance and recurrence. Costs rapidly accrue with the many and varied tests and procedures used in the full work-up of patients combined with the repeated visits and re-visits to the clinic to monitor for the high probability return of this disease. Cystoscopy, the current gold standard used widely in the detection and management of bladder cancer, is an invasive and expensive endoscopic evaluation of the bladder requiring local or general anaesthesia, expensive equipment and expertise. Patients often find the procedure disagreeable and time-consuming, and reluctance to undergo cystoscopy can impact patient compliance with guideline-recommended surveillance protocols, which may increase disease progression.

Comparatively, the non-invasive collection of a urine sample for a CxbM test carries a significantly lower burden for patients in terms of time away from work, anxiety, pain and discomfort during and after the procedure and is likely to lead to an increase in patient compliance with physician recommendations. In addition, the more accurate the urine biomarker test is, the more cost-effective it is in the surveillance of recurrent UC, and the more acceptable it becomes to patients as an adjunct or alternative to routine cystoscopy.

Read the full BMC Urology paper here:
https://bmcurol.biomedcentral.com/track/pdf/10.1186/s12894-020-0583-0

ENDS

[1] Kavalieris L, O'Sullivan P, Frampton C, et al. Performance Characteristics of a Multigene Urine Biomarker Test for Monitoring for Recurrent Urothelial Carcinoma in a Multicenter Study. J Urol. 2017;197(6):1419-26;
Lotan Y, O'Sullivan P, Raman JD, et al. Clinical comparison of noninvasive urine tests for ruling out recurrent urothelial carcinoma. Urol Oncol. 2017;35(8):531 e15- e22.

Company Announcement
12 February 2020

For more information contact:

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

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. Its Cxbladder suite of non-invasive, simple to use and accurate diagnostic tests provide actionable results, and better detection and management of urothelial 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.

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 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 allows urologists to monitor bladder cancer patients for recurrence of the disease. 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.

ABOUT Cxbladder Resolve www.cxbladder.com
Cxbladder Resolve identifies those patients who are likely to have aggressive or more advanced bladder cancer. Cxbladder Resolve, when used as part of the primary evaluation of haematuria and/or in conjunction with other Cxbladder tests (Triage, Detect), is designed to assist clinicians by accurately identifying patients with a high probability of having high grade or late stage bladder cancer, for whom alternative or expedited treatment options may be warranted, or who can be prioritised for further investigation in high throughput settings.

Refer to www.cxbladder.com for more information.