Pacific Edge Ltd
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PACIFIC EDGE LTD
CANCER DIAGNOSTICS COMPANY

Introducing a new class of cancer detection and management tools

Pacific Edge's state-of-the-art suite of bladder cancer detection and management tests are noninvasive, highly effective, and more accurate than other urine-based cancer diagnostic tests, and are now being adopted into the standard of care.

Bladder cancer is the ninth most common cancer globally and the fifth most common in the United States. Although bladder cancer can often be treated successfully, it has one of the highest recurrence rates. Lifelong surveillance following treatment and an arduous regime of expensive and invasive tests over the lifetime of the disease drive bladder cancer to have the highest cost per patient of all cancers.

To address this problem, Pacific Edge provides cost-effective, highly accurate and noninvasive diagnostic tests that can be used across the clinical pathway for bladder cancer. These products are built from proprietary genetic databases, which are used to identify diagnostic and prognostic biomarkers for cancer.

The company's products, all branded Cxbladder, are a new class of bladder cancer detection and management tests that detect urothelial cancers including those in the upper urinary tract and renal pelvis, which are notoriously difficult to identify (**Fig. 1**). Currently available commercially in Australia, New Zealand, Singapore and the United States, Cxbladder enables physicians to make more informed decisions on patient care. "Reducing the total number of procedures and the number of invasive procedures, resulting in lower cost, better allocation of limited healthcare resources and improved outcomes for patients, makes the difference," said David Darling, CEO of Pacific Edge.

One-stop shop

The current gold standard for the diagnosis of bladder cancer is cystoscopy, an invasive endoscopic procedure that allows doctors to examine the lining of the bladder and the urethra. The discomfort and anxiety experienced by patients and the relatively poor performance of cystoscopy have prompted the development of more accurate, less invasive urine-based diagnostic tests. These tests would not only address this large unmet need but also provide meaningful improvements for the initial evaluation and ongoing assessment of recurrent bladder cancer, as well as improve patient outcomes.

Cxbladder encompasses a suite of four tests to meet different clinical needs. Cxbladder Detect and Cxbladder Triage are designed for the detection and elimination of bladder cancer in patients who present to their physician with the most common symptom: hematuria, that is, blood in the urine. Cxbladder Monitor is optimized to rule out those patients with a low risk of bladder cancer recurrence following treatment, and Cxbladder Resolve is designed to identify patients likely to have high-grade or late-stage bladder cancer.

Fig. 1 | Cxbladder at the Pacific Edge laboratory. This new class of noninvasive, highly effective bladder cancer detection tests is commercially available in Australia, New Zealand, Singapore and the United States.

Cxbladder Detect quantifies the presence of RNA biomarkers, the increased expression of which is correlated with the presence of bladder cancer. In particular, this test is designed for high-risk patients who present with hematuria. A multicenter, prospective trial of 485 patients with a recent history of gross hematuria (visible blood in the urine) confirmed that Cxbladder Detect outperforms comparative tests as an adjunct to cystoscopy, with a sensitivity of 82%, a specificity of 85% and a negative predictive value of 97%.

Cxbladder Triage combines genomic, phenotypic and clinical biomarkers in patients with hematuria. This test is the first of its kind, and is particularly suitable for low-risk patients for whom a more extensive evaluation may not be required. A clinical study of 587 patients presenting with gross hematuria demonstrated that Cxbladder Triage has a sensitivity of 95% and a negative predictive value of 98.5%. The study also showed that 40% of patients were accurately triaged out with a low probability of urothelial carcinoma.

Cxbladder Monitor accurately rules out recurrent urothelial carcinoma. A recent study showed that Cxbladder Monitor, with a negative predictive value of 97% and a sensitivity of 93%, outperformed all other FDA-approved urine tests compared in this study for ruling out patients with a low risk of recurrent disease. Cxbladder Monitor reduces the need for regular cystoscopy and other expensive, invasive procedures, which enables physicians to focus their efforts on individuals who are at a higher risk of recurrence and require further clinical workup.

The fourth test in this series is Cxbladder Resolve, which is designed to identify patients likely to have high-grade or late-stage bladder cancer. When selecting exclusively for high-grade or late-stage tumors, the test's sensitivity is 96% and its specificity is 93%, which enhances the physician's clinical resolution, enabling the accurate segregation of patients with aggressive or advanced-stage disease.

Saving lives, saving costs

Bladder cancer currently affects more than 3.4 million people worldwide. In the United States alone, the majority of the 800,000-plus people living with bladder cancer will visit clinics regularly for recurrence monitoring, amounting to approximately 2.4 million clinic visits each year. Cxbladder can effectively prevent up to 80% of these patients from undergoing expensive and invasive workups, increasing patient compliance and helping improve their outcome.

In the detection and monitoring for recurrence settings, Cxbladder is projected to spare up to 80% of patients with hematuria in the United States from costly and invasive detection procedures, which can total more than $4,000 per person. "Cxbladder is revolutionizing the way urothelial cancer is detected and managed, helping to change clinical practice internationally. The recent addition of Cxbladder to the guidelines of a large public healthcare provider in New Zealand is a global first and validates the utility of our tests," Darling said.

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