



NZX ANNOUNCEMENT 15 JUNE 2011

Cxbladder[®] KIT RECEIVES REGULATORY REGISTRATION IN AUSTRALIA

Pacific Edge Limited's flagship product **Cxbladder[®]** has received registration under the Australian regulatory body Therapeutic Goods Administration (TGA). The TGA registration is effective immediately and permits Pacific Edge and their Australian commercialisation partner Healthscope, to market and sell **Cxbladder[®]** to all segments of the Australian market.

TGA registration represents an important milestone in the Company's commercialisation program. Before any medical device can be supplied to customers or end users in Australia, the device must be included in the Australian Register of Therapeutic Goods (ARTG). The ARTG is regulated by the Australian Therapeutic Goods Administration (TGA). Regulatory approval is a key element in today's healthcare environment to ensure product compliance and allow new products to be effectively and safely used in the market.

Pacific Edge has recently signed a licensing agreement with Healthscope Pathology, Australia's leading private health care provider, to commercialise **Cxbladder[®]** in Australia. A prominent private health care provider, Healthscope operates in every Australian State and Territory, as well as in Asia. Its reach of facilities firmly places Healthscope as the second largest Australian private hospital provider operating 44 private hospitals. The company includes a leading pathology business with facilities in Australia, New Zealand, Singapore, Vietnam and Malaysia; a growing medical centres division with over 48 clinics; and a diagnostic imaging division centred in major hospitals. This milestone will see **Cxbladder[®]** marketed extensively in Australia this year with product and services available to both clinicians and general practitioners. There are approximately 300 urologists in Australia and New Zealand of which 240 are resident and practicing in Australia.

Globally bladder cancer has the 9th highest incidence however it is the cancer with the 4th highest for men. One of the early symptoms of bladder cancer is the presence of blood in the urine, haematuria. People with haematuria often present to their general practitioner before being referred on to a urologist.

Treatment of bladder cancer incurs the highest total medical costs of any cancer, and in the United States this figure is approaching US\$200,000 per patient from detection until death. In Australia there are expected to be in excess of 50,000 people presenting to their healthcare provider this year with blood in their urine, often a precursor to bladder cancer, and it is anticipated that the Australian healthcare system could invest in excess of \$50 million per annum in investigating haematuria. **Cxbladder[®]** is expected to completely replace cytology and be used to complement cystoscopy in the clinical care path for patients presenting to clinicians with haematuria.

The Australian market is seen to be a key market for Pacific Edge as it is effectively our home market and enables the company to get an early start to revenue generation by being able to interact directly with New Zealand and Australian urologists and general practitioners from our base in Dunedin.

Cxbladder[®]

Cxbladder[®] is a non-invasive, accurate test that enables the early detection of bladder cancer from a small volume of urine. It provides general practitioners and urologists with a quick, cost effective and accurate measure of the presence of the cancer, and provides urologists with the opportunity to reduce their reliance on the need for invasive tests such as cystoscopy. The recently completed multi-centre international clinical study recruited 467 patients from Australia and New Zealand. Results show that **Cxbladder[®]** outperforms all of the benchmark technologies in the trial and detected nearly all of the tumours of concern to a urologist; greater than 95% of all late stage and high grade tumours.



Pacific Edge Limited (NZX: PEB):

Pacific Edge (PE) is a New Zealand based biomedical and diagnostics company specialising in the discovery and commercialisation of diagnostic and prognostic technology for the early detection and monitoring of cancer. Products in development and in clinical trials are accurate and simple to use genomic and proteomic tools for the earlier detection, improved characterisation and better management of gastric, bladder, colorectal, endometrial cancers and melanoma. The company has recently completed and released its first product for the detection of bladder cancer, **Cxbladder**[®].

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