

## ASX ANNOUNCEMENT

### CELLMID DIAGNOSTIC LICENSES UPDATE

- Cellmid licensees have made significant progress commercialising lung and bladder cancer tests using midkine
- Quest validates lung cancer diagnostic test on the Luminex commercial platform
- Pacific Edge Ltd gains CLIA registration for US commercial lab

**SYDNEY, Tuesday, 26 March 2013: Cellmid Limited (ASX: CDY)** provides the following market update on two cancer diagnostic tests using the company's proprietary midkine technology under license. The Company is pleased to advise that both of its licensees have achieved significant milestones in their product development and commercialisation programs.

#### **Lung Cancer License - Quest (Celera)**

Cellmid signed a license agreement with Quest (Celera) in October 2009 enabling Quest to include midkine as one of the biomarkers in lung cancer tests. The license covers using midkine for the early diagnosis, prognosis, disease monitoring and management of lung cancer. The terms of the agreement provide for a milestone payment at the time of regulatory clearance for the lung cancer test, and royalties to be paid semi-annually.

Cellmid has received its annual update on the progress made in the development of the lung cancer test. As a significant milestone on the road to market, Quest (Celera) has reported that they have transferred and validated their six-marker based lung cancer test from ELISA format onto the commercial Luminex platform. Luminex is widely used by pathology labs internationally, and should provide the ideal platform for product launch.

Cellmid has been advised that the next step is clinical validation. Samples obtained from the National Cancer Institute sponsored chest X-Ray screening Prostate, Lung, Colorectal and Ovarian Trial (PLCO) will be used to demonstrate clinical accuracy of the test. Further, these validation studies are currently initiated. Quest (Celera) noted that they "continue to work diligently" to use midkine in the company's lung cancer tests, particularly for the diagnosis of indeterminate pulmonary nodules identified through CT scan or chest x-ray.

Lung cancer is the leading cause of cancer death in the United States. Currently CT scans are performed to diagnose lung cancer; however these are expensive, lack the required accuracy and have a poor safety profile. Cost effective, safer and more accurate methods, such as Quest's lung cancer test, are urgently needed to improve survival, limit side effects and reduce costs.

Cellmid is pleased to see the significant progress made by Quest (Celera) in its commercialisation endeavours of the important lung cancer diagnostic test.

## Bladder cancer license - Pacific Edge Limited

Cellmid signed a license agreement with Pacific Edge Limited in 2010 for the use of midkine as one of the biomarkers in their bladder cancer test (*Cxbladder*). Pacific Edge has achieved solid progress since the license was signed and has recently received CLIA<sup>1</sup> registration of its Pennsylvania labs. This clears the way for the launch of *Cxbladder* in the United States.

This is a significant commercial milestone for Pacific Edge as the CLIA registration means that it can roll-out a sales and marketing program around the product within the next few months. Pacific Edge expects revenues to grow gradually during 2013, as outlined in a recent market presentation by company CEO David Darling.

The license between Cellmid and Pacific Edge provides for a milestone fee payable in shares, which is due on the first sale of *Cxbladder* in the USA. Royalties on revenues are expected to be paid to Cellmid semi-annually.

Bladder cancer is one of the most common forms of malignancy. In the United States around one million patients present annually with haematuria; of these, 68,000 are diagnosed with bladder cancer. Once treated, patients currently undergo frequent, painful and expensive cystoscopies (urethral endoscopies) to monitor reoccurrence. Pacific Edge's *Cxbladder* has the potential to replace cystoscopy over time as a preferred method of patient monitoring tool.

*Cxbladder* has shown outstanding performance in clinical studies to date, with 100% sensitivity and 85% specificity in late stage bladder cancer. This specificity is expected to increase in a monitoring setting. The test can also be used to differentiate between high and low grade cancers.

*Cxbladder* was the subject of a comparative study of 485 patients and it significantly outperformed other commercially available bladder cancer tests<sup>2</sup>. Importantly, it has identified 20 cases of bladder cancer that were not identified by cystoscopy during clinical work-up.

Cellmid CEO, Maria Halasz, said that Pacific Edge is a great example of a small diagnostic company making a major difference in the way cancer is diagnosed, monitored and managed. Early diagnosis is well documented to be a significant contributor to better cancer survival and it is expected that a simple urine or blood test using midkine will greatly contribute to improved patient outcomes.

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<sup>1</sup> Clinical Laboratory Improvement Amendment, CLIA, sets standards and issues certificates for clinical laboratory testing in the United States. It is administered by the US Centre for Medicare and Medical Devices, CMS.

<sup>2</sup> O'Sullivan et al. (2012). "A multigene urine test for the detection and stratification of bladder cancer in patients presenting with hematuria." *J Urol* **188**(3): 741-747.



### **Cellmid Limited (ASX: CDY)**

Cellmid is an Australian biotechnology company developing innovative novel therapies and diagnostic tests for inflammatory diseases, heart attack and cancer. Cellmid holds the largest and most comprehensive portfolio of intellectual property related to midkine and midkine antagonists globally. The Company's most advanced development programs involve using its anti-midkine antibodies for the treatment of cancer as well as inflammatory and autoimmune disorders. In addition, Cellmid is commercialising midkine as a biomarker for cancer diagnosis. Elevated midkine concentration in the blood and other body fluids is strongly indicative of cancer. Cellmid's first product, the MK-ELISA, is a blood test that sensitively and accurately measures serum midkine levels.

### **Midkine (MK)**

Midkine is a multifunctional growth factor that is highly expressed during embryonic development. Midkine modulates many important biological interactions such as cell growth, cell migration and cellular adherence. These functions are relevant to cancer, inflammation, autoimmunity, ischemia, nerve growth/repair and wound healing. Midkine is barely detectable in healthy adults and only occurs as a consequence of the pathogenesis of a number of different disorders. Midkine expression is often evident very early in disease onset, even before any apparent physical symptoms. Accordingly, midkine is an important early marker for diagnosing cancers and autoimmune diseases. Finally, because midkine is only present in a disease context, targeting midkine does not harm normal healthy tissues.