

#### **ASX ANNOUNCEMENT**

# ANNUAL REPORT ON CELERA (QUEST) LICENSE

- Midkine is confirmed to be part of Celera's six marker lung cancer diagnostic panel
- New study using the test shows 94% specificity in correctly classifying non-malignant nodules
- 1.7 million smokers over 55 may be tested annually

**SYDNEY, 5 March 2012: Cellmid Limited (ASX: CDY)** has received its second annual report from Celera-Quest Diagnostics in relation to its lung cancer diagnostic licence (details of the license are included at the end of this announcement). The report confirmed that midkine is one of the six biomarkers on Celera's lung cancer diagnostic panel.

Results of a recent study have also been provided by Celera-Quest Diagnostics demonstrating that the six marker lung cancer panel showed 94% specificity (at 70% sensitivity) in accurately classifying non-malignant nodules identified during CT (computed tomography) scanning of a high risk smoker population.

Even though the rate of smoking is declining there are an estimated 94 million current and past smokers in the United States who are at risk of contracting lung cancer. Of this group those aged over 55 are at greatest risk. Mortality caused by lung cancer can be markedly reduced if cancerous nodules are detected and removed very early; however it is usually the case that once patients are symptomatic, the cancer has already spread from its initial site, thereby reducing the chances of successful treatment.

Population screening of at-risk groups using imaging such as CT scanning has been proposed as one way to reduce lung cancer mortality. This proposal was recently tested by the US National Institute of Health (NIH) in a large-scale study of 53,454 current and exsmokers aged 55-74, which found that screening by CT scanning reduced mortality by 20% in 6 years<sup>1</sup>.

While this is some good news for the seven million American smokers over 55, the low specificity of CT scanning is still a concern as the same study showed that 25% of the solitary nodules identified by CT scan proved to be non-cancerous after lung biopsy (75% specificity).

Unnecessary biopsy of otherwise benign nodules creates additional costs and significant morbidity for this already very large patient group. Celera-Quest Diagnostics' six marker lung cancer panel with its 94% specificity may therefore become a useful adjunct to imaging. It may assist in further clarifying the diagnosis in patients who have tested positive during their CT screening (estimated to be 1.7 million in the highest risk group).

<sup>&</sup>lt;sup>1</sup> Rduced Lung-Cancer Mortality with Low Dose Computed Tomographic Screening, The N Eng J Med, vol.365 No5 4 Aug 2011

In order to commercialize the lung cancer panel the assay is currently being transferred to a multiplex format. With Quest Diagnostics' extensive distribution capabilities it will most likely be sold as a Lab Developed Test (LDT). In addition to the specific application for high risk screening, Celera-Quest Diagnostics has confirmed that it continues with the development of additional lung cancer tests using midkine.

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## License between Cellmid Limited and Celera-Quest Diagnostics for lung cancer

In October 2009 Cellmid Limited licensed to Celera Corporation midkine as a biomarker for the early diagnosis, prognosis and disease monitoring of lung cancer to be used in Celera's proprietary biomarker panel. The terms of the license are confidential but involve upfront and milestone payments and royalties on product sales. In May 2011 Celera Corporation was acquired by Quest Diagnostics, one of the largest diagnostics companies in the world. The acquisition was share based and did not affect the terms of the license between Celera Corporation (now Celera-Quest Diagnostics) and Cellmid Limited.

## 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 clinical development program is for the treatment of acute myocardial infarction (AMI) utilising the midkine protein. Cellmid is also developing anti-midkine antibodies for the treatment of inflammatory and autoimmune disorders. In addition, Cellmid is commercialising midkine as a biomarker for cancer diagnosis, prognosis and as a surrogate marker in clinical drug development. 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. It is a GMP manufactured and CE marked test which has become the gold standard in midkine measurement since its launch in November 2011.

## 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.