

**ASX ANNOUNCEMENT**

**RESULTS OF COMPLETED CK3000 DIAGNOSTIC STUDY**

- **Largest ever study of midkine in healthy volunteers – 574 individuals**
- **Results are pivotal in any regulatory submission for midkine diagnostics**
- **Elevated midkine predictive of serious illness in a small group of asymptomatic outliers**

**SYDNEY, Wednesday 18 December 2013: Cellmid Limited (ASX: CDY)** has completed its two year long CK3000 program investigating normal serum concentrations of midkine (MK) in the largest ever study of healthy volunteers involving 574 individuals.

The study results confirmed interim findings of “healthy” MK levels in a statistically meaningful population size and provided further insights into a small group of ‘outliers’, asymptomatic individuals presenting with elevated MK levels. The results are expected to be pivotal in future regulatory submission for stand alone midkine diagnostic tests for monitoring wellness, disease recurrence or treatment efficacy in any cancer.

Cellmid commenced CK3000 in 2011 in collaboration with Kumamoto University to determine, in a statistically meaningful definitive study suitable for regulatory submission, the normal MK ranges for apparently healthy individuals.

A key to the study was the concurrent measurement of other important biomarkers and the recording of extensive lifestyle data. Only individuals that tested within the normal ranges for other biomarkers qualified to participate in the MK arm of the study.

These apparently healthy subjects had their blood samples analysed in the Kumamoto hospital pathology laboratory. Analysis included standard blood tests for kidney and liver function, in addition to markers for inflammation (CRP), cholesterol (LDL/HDL) and diabetes (HbA1c).

Information on the subject’s age, sex, alcohol and tobacco use was also collected. Blinded serum samples were tested for MK levels separately in the laboratories of Dr Yukio Ando within the Graduate School of Medical Sciences at Kumamoto University using Cellmid’s CE-marked and independently validated MK-ELISA.

Over the two years 627 sequential serum samples were collected and tested from anonymous donors participating in a unique ‘wellness’ blood-screening program at

Kumamoto University Hospital. The 627 samples came from 574 different individuals (349 female, 225 male, ages 15-87); 36 individuals were tested more than once.

Of these apparently healthy subjects 96.3% had serum MK concentrations under 1000pg/mL, with 90.7% below 500pg/mL. The frequency distribution and population statistics were in close agreement with previous smaller normal population studies published in the peer-reviewed literature. The data also closely resembled that collected by BioGenes GmbH (Berlin, Germany) during validation studies of Cellmid's MK-ELISA kit.

MK levels above 1000pg/mL were considered to be abnormal and were investigated further. For these 21 individuals (3.7% of all subjects) elevated MK showed no correlation with age, sex, smoking or alcohol intake, and nor did any of the 21 subjects have elevated CRP, HbA1c or high LDL. Liver and kidney function tests were also normal.

The ethics approvals granted for the study allowed the follow up on six of the 21 otherwise healthy subjects with elevated MK as these individuals had accessible patient records at Kumamoto Hospital.

Critically, 4 of these 6 subjects had in the past been admitted to the hospital for cancer (glioblastoma, osteosarcoma), autoimmune disease (rheumatoid arthritis) and an acute inflammatory condition. The reason for hospital admission of the other two subjects was not recorded.

"Finding a history of cancer and serious inflammatory disease that explains high MK levels in apparently healthy subjects is powerful validation of the value of MK as a disease biomarker," said Darren Jones, Head of Product Development at Cellmid. "This is especially so in the absence of any other indication of disease" he added.

"We currently have more than a dozen diagnostic collaborations in various disease indications and this data set will have significant impact on interpretation of patient data collected in those studies" said CEO of Cellmid Maria Halasz.

Full findings from the CK3000 program will be the subject of a peer-reviewed publication co-authored by Kumamoto University and Cellmid's scientific team.

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

Cellmid is an Australian biotechnology company developing innovative novel therapies and diagnostic tests for inflammatory diseases 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 and inflammatory diseases. 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. For further information please see [www.cellmid.com.au](http://www.cellmid.com.au).

### **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.