



**Living Cell Technologies Ltd**  
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## COMPANY ANNOUNCEMENT

### **LCT granted approval to manufacture xeno products for human use**

*19 December 2006, Melbourne, Australia:*

Living Cell Technologies Ltd (ASX:LCT) today announced it has received a licence from the New Zealand Government to manufacture a novel animal cell product for humans under Good Manufacturing Practice (GMP).

The NZ regulator MedSafe issued a formal letter to LCT recommending a *Licence to Manufacture Medicines* be issued which will allow the use of its xenotransplant products in human patients. The facility will be used to manufacture cell therapy products including DiabeCell® - LCT's diabetes product.

The scope of the GMP accreditation includes the company's proprietary micro-encapsulation process and also the manufacture and preparation of free islets from neo-natal pigs.

"GMP accreditation is a significant milestone and is a necessary requirement to begin LCT's clinical trial program," said LCT Managing Director, Dr Paul LJ Tan.

"As far as we know, LCT possesses the only accredited GMP facility to make xeno porcine products and will be able to manufacture its products in accordance with the regulations of any regulatory jurisdiction throughout the world."

"This is a strong vote of confidence in xeno-based cell research and the potential of LCT's products to significantly address the global diabetes epidemic," said Prof Bob Elliott, Medical Director.

This significant milestone is the first and most fundamental part in a three step process to obtain approval for a human clinical trial in New Zealand in 2007. LCT must now receive a 'Recommend for Approval' from MedSafe to conduct the clinical trial and final ethics approval.

The accreditation has been granted after a rigorous audit process.

DiabeCell® is a porcine islet cell transplant therapy for the treatment of insulin-dependent diabetes. The neo-natal pig cells produce insulin and help regulate blood glucose levels appropriate to the amount of glucose detected in the blood stream of the diabetic recipient.

After a preliminary consultation with Medsafe NZ, LCT submitted an application earlier this year to conduct the DiabeCell® clinical trial on eight long standing Type 1 (insulin-dependent) diabetics.

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**Note:** Xeno-based cell products: *The use of living, primary animal cells for human treatment.*  
**About Living Cell Technologies:** *Living Cell Technologies Ltd (ASX: LCT) develops live cell therapy products to treat life threatening human diseases without requiring the use of toxic drugs to prevent immuno-rejection.*