



**Living Cell Technologies Ltd**

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**COMPANY ANNOUNCEMENT**

**Regulatory Review allows LCT Diabetes Clinical Program to Proceed**

*17 April 2007, Auckland, New Zealand and Melbourne, Australia:*

Living Cell Technologies Ltd (ASX:LCT) after rigorous international review has received authorization from the New Zealand regulator MedSafe to advance its program to conduct a Phase I/IIa clinical trial of its DiabeCell<sup>®</sup> diabetes product in New Zealand.

DiabeCell<sup>®</sup> is a porcine islet cell product for the treatment of insulin-dependent diabetes. The pig cells are injected into the body without any immunosuppression and produce insulin to help regulate blood glucose levels appropriate to the amount of glucose detected in the blood stream of the diabetic recipient.

This approval enables LCT to apply for Regional Ethics Committee consideration, which is the step before formal approval to start the clinical trial. The NZ Health Research Council's Gene Technology Advisory Committee (GTAC) invited international experts in their strenuous 7 month review across ethical and cultural considerations, safety, public health and scientific data.

"This MedSafe recommendation confirms that the standards developed by LCT to meet regulatory requirements withstand international scrutiny," said Dr Paul Tan, Chief Executive Officer.

"LCT is the only company to have the essential requirements of an appropriate biocertified pig herd, GMP manufacturing facilities and monitoring protocols to proceed with such a trial," commented Dr Tan.

LCT's GMP manufacturing facilities were audited and approved by MedSafe in December 2006. LCT has also received independent validation from international laboratories on its viral testing procedures. LCT's diagnostic laboratory for viral testing has also been audited by New Zealand authorities.

In 2005, the New Zealand government conducted a large bioethics public consultation, which recommended that xenotransplantation should proceed on a case by case basis, and this prompted LCT's application.

The capabilities to meet current stringent regulatory standards have not been met by any other xenotransplantation company anywhere in the world. As such, LCT has set the standard for this type of research in New Zealand.

"DiabeCell<sup>®</sup> offers considerable advantages over other available treatments as there is no need for immuno-suppressive drugs, and the supply of cells from LCT's natural biocertified pig herds are readily available, unlike human organ donors," said LCT Medical Director, Prof Bob Elliott.

New Zealand Trade and Enterprise (NZTE), which has worked closely with LCT to support their development and commercialisation programme, says approval for phase I/IIa clinical trial in New Zealand is a significant achievement for the company.

"It has taken an enormous amount of time, effort and resource to get approval to move to clinical trial, but today's announcement certainly validates LCT's world leading diabetes xenotransplantation capabilities," says NZTE Trade Commissioner and Consul General, Shona Bleakley, based in Melbourne.

LCT's application is to conduct the clinical trial of its DiabeCell® product on eight long standing Type 1 (insulin-dependent) diabetics. The clinical trial is expected to be approximately 12 months in duration. This will then be followed by a larger pivotal trial.

The trial will be conducted at a New Zealand hospital and involves the simple injection of encapsulated islets into the abdomen of the diabetic patients. It is anticipated that the trial would start by Q4 2007.

<b>Further information:</b> Images/graphics available upon request – <a href="mailto:lct@lctglobal.com">lct@lctglobal.com</a>		
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**About Living Cell Technologies: [www.lctglobal.com](http://www.lctglobal.com)**

*Living Cell Technologies Ltd (ASX: LCT) develops live cell therapy products to treat life threatening human diseases. The ASX listed, vertically integrated company operates globally through offices in New Zealand and Australia. LCT focuses on developing treatments where healthy living cells are injected into patients to replace or repair damaged tissue, without requiring the use of toxic drugs to prevent rejection. The company's product portfolio focuses on treatments for people with insulin-dependent diabetes, neurological disorders and haemophilia.*

**MedSafe: [www.medsafe.govt.nz](http://www.medsafe.govt.nz)**

*Medsafe is the New Zealand Medicines and Medical Devices Safety Authority. It is a business unit of the Ministry of Health and is the authority responsible for the regulation of therapeutic products in New Zealand. In carrying out its functions, Medsafe is accountable to the Ministry of Health, and through the Ministry to the Minister of Health. Ethics Committee approval, equivalent to approval from the Institutional Review Board in the US, is required for all research involving humans. Only one ethics committee review is required per study in New Zealand.*

**Background Information:**

Scientific papers relating to DiabeCell® are available for download on the LCT website at <http://www.lctglobal.com/scientificarticles.php>