



Living Cell Technologies Limited

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LCT Reports Major Step Forward for Islet Transplantation in Diabetes Patient

30 March, 2007, Melbourne, Australia:

Living Cell Technologies Limited (ASX: [LCT](#)) today announced it has published evidence outlining the survival and identification of live porcine islet cells and insulin production in a human patient 10 years after receiving a pig islet cell transplant.

The scientific paper published in the March issue of the international journal *Xenotransplantation* outlines how LCT has demonstrated the long-term safety, viability and function of its encapsulated porcine islets in a human patient over an extended period of time, without the use of immunosuppression.

In 1996 a 41 year old diabetic was injected with LCT's prototype diabetes product containing pig islet cells to help regulate his blood glucose levels and control of diabetes. The transplanted cells helped reduce the patient's insulin requirement by 34% for over a year, which provided better control and overall well-being. By 2005 the patient's glycated hemoglobin levels remained lower than the pre-transplant levels pointing to improved long-term control of blood glucose levels.

Ten years later the patient suggested that he was still obtaining benefit from the transplant. LCT scientists assumed that the cells would not be alive or functioning after that period of time, but the patient convinced LCT scientists to organise for a laparoscopy to check. This resulted in finding both living and functioning pig islet cells in his abdomen.

"This has never been achieved before. It is a profound step forward for safe, effective and long-term diabetes control and shows the ability for pig cells to survive inside a human for an extended period of time and without immune suppression," commented Prof Bob Elliott, LCT Medical Director.

Dr Christina Buchanan, a biochemist from the University of Auckland and an expert in insulin, conducted the analysis to ensure that the insulin detected in the patient's blood samples were unequivocally pig and not human insulin – the final proof of efficacy.

Dr John Court, a diabetologist and scientific advisor to LCT said: "This is only one patient's experience but it does show that pig cells can survive at least ten years in a micro-capsule coating and continue to release insulin into the patient's bloodstream."

LCT has significantly advanced the encapsulation process since the 1996 clinical trial and there is an even greater understanding and control over the longevity and robustness of the encapsulation process, as well as the porcine islet cells. The product is produced under a GMP manufacturing license.

LCT will be trialing the DiabeCell® pig islet cell transplant in patients in a phase I/IIa clinical trial, expected to begin in Quarter 2, 2007. In addition, LCT is awaiting approval to conduct an additional trial in New Zealand this year with a different treatment protocol. Subsequent trials in the US or Europe are intended following initial results from these studies.

The trial will involve the simple injection of encapsulated neo-natal pig islet cells into the peritoneal (abdominal) cavity of the diabetic patients. The procedure is quite simple and carried



out under local anaesthetic. Patients will then be monitored by LCT's well established protocols, which are in accordance with international xenotransplantation guidelines.

"This is strong evidence that LCT's DiabeCell® product holds significant potential to address the key issues of finding renewable donor cells and not using immunosuppression, as outlined in the National Institutes of Health (USA) and Juvenile Diabetes Research Foundation (JDRF) strategic plans," said Dr Paul Tan, LCT's CEO.

"LCT's clinical trial program intends to test three different treatment regimens, in order to find the most appropriate, long-lasting and effective transplant possible," Dr Tan said.

DiabeCell® is a porcine pancreatic cell product 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.

Extensive pre-clinical testing of DiabeCell® in animal models has shown no adverse effects with any dose or repeated transplants, extended survival of the islets, a significant reduction in insulin requirements, and prolonged insulin independence in some individual animals.

Contacts: Images available – lct@lctglobal.com Interviews with the patient can be arranged		
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Further Information:

About the transplant:

- A 41 year old Caucasian male (a type 1 diabetic for 18 years) was injected with biocapsules containing porcine islets in 1996 as part of an approved clinical trial in New Zealand. The early prototype of LCT's DiabeCell® product reduced the patient's insulin dosage in the first year by as much as 34 per cent and better control of his diabetes was achieved.
- A laparoscopy nine and a half years later displayed numerous opacified capsules attached to the peritoneum. On biopsy, these capsules contained viable islets showing glucagon and sparse insulin immune staining cells.
- After an oral glucose load, a small amount of porcine insulin could be detected in the blood of the patient.

About Living Cell Technologies: www.lctglobal.com

Living Cell Technologies Ltd (ASX: LCT) develop live cell therapy products to treat life threatening human diseases. The ASX listed, vertically integrated company operates globally and 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 and neurological disorders.

About the journal *Xenotransplantation*:

Xenotransplantation is an international journal published bi-monthly which provides its readers with new findings in the field of organ and tissue transplantation across species barriers. Reference to the publication online: [Xenotransplantation 2007 14: 157-161.](#)