



Living Cell Technologies Ltd

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COMPANY ANNOUNCEMENT

**Diabetes Patient Successfully Transplanted in
World-first DiabeCell® Trial**

14 June, 2007: Melbourne, Australia and Auckland, New Zealand:

Key Points:

- First type I diabetes patient was successfully dosed with DiabeCell® pig cell implant
- DiabeCell® therapy is aimed at controlling the dangerous blood glucose levels and long-term secondary complications affecting people with type I diabetes
- LCT is conducting the clinical trial according to stringent international regulatory guidelines

Living Cell Technologies Ltd (ASX:LCT) is pleased to announce it has successfully transplanted the first of six type I (insulin dependent) diabetic patients in a world-first Phase I/IIa clinical trial under current regulatory standards, using its DiabeCell® pig islet cell transplant.

Patients in the Phase I/II trial will receive two low doses of the pig islet cells (DiabeCell®) every 6 months over a 12 month period, followed by a further 12 month study addressing the level of its therapeutic effect. In LCT's dose ranging clinical program for DiabeCell®, recipients in this first trial are given the lowest clinically effective dose to demonstrate safety. The dosing is repeated for additional clinical benefit.

The company hopes to commercialise the product for general use by 2012.

"DiabeCell® has the potential to provide a very important new treatment for insulin-dependent diabetics, providing a better control of dangerous blood glucose levels and long-term secondary complications. If the trial is successful, a major stride in developing a better treatment for diabetes will have been accomplished," commented Professor Bob Elliott, LCT's Medical Director.

DiabeCell® is a pig pancreatic islet cell product that secretes insulin in response to the patient's blood glucose levels. People with type I diabetes are not able to produce their own insulin because their pancreas cells are not functioning. DiabeCell® has been uniquely developed with a gel that forms a tiny capsule around the cells and prevents the patient's immune system from destroying the transplant.

"This transplant launches LCT's lead product into the clinic and moves the Company into a phase for growth in the value of our business," said Dr Paul Tan, LCT CEO.

The trial is being held at the prestigious Sklifasovsky Institute in Moscow, which has extensive experience in organ transplantation and xenotransplantation. Boston-based GenyResearch Group acts as the project manager to ensure all elements of the trial adhere to international regulatory standards.

The company has been developing the necessary components to obtain regulatory approval for over a decade, with LCT now the only company with the current capabilities of owning a bio-certified pig herd for supply of the cells, a GMP manufacturing unit to prepare the treatment and a specialised monitoring laboratory for assessing transplant recipients. The company also holds a strong patent portfolio in markets where DiabeCell® will be commercialised.

Under the agreement, LCT will supply the cells and retain all IP and commercial rights to the product. The Russian partners will cover all costs of conducting the trial.

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About Living Cell Technologies: 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 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. LCT owns a biocertified pig herd for the supply of medical-grade cells and is developing products to treat diabetes and neurological disorders.

APPENDIX - Further Information:

Trial Name: A Phase I/IIA, Open-Label Investigation of the Safety and Effectiveness of **DiabeCell[®]** (Immunoprotected alginate-encapsulated) Porcine Islets for Xenotransplantation in Patients with Type 1 Diabetes. Protocol LCT/DIA-07R

Trial centre details:

- Sklifasovsky Institute.
- Clinician – Professor Andrej Guljaev, surgeon, Chief of Innovative Surgical Technology Department
- Professor Anatolij Panov, Director of Institute of BioMedical Problems
- Geny Research Group (US) – Contract Research Organisation

Clinical Trial Protocol:

- LCT's proposal for the human clinical trial of DiabeCell[®] in Russia will include six Type 1 (insulin-dependent) diabetics in two stages.
- There will be 6 adult patients treated with females over 35 years old and males over 25 years of age.
- The candidates must have had type 1 diabetes for at least 10 years with no other complications and provide full consent for follow-up monitoring.
- The patients will receive an initial transplant (a simple injection of encapsulated islets into the peritoneal cavity of the patient) followed by a second transplant six months later.
- The first transplant dose will be equivalent to 5,000 IEQ (islet equivalents/kg). The second transplant will be a further 5,000 IEQ's.
- The procedure is minimally invasive and will be administered into the abdomen through a laparoscope.

Primary Safety Endpoints

- Occurrence of hypoglycaemic episodes in the post-transplant period in comparison with those occurring during the 8-week run-in period.
- Occurrence of perioperative reactions (e.g. wound infections, local tissue reactions to the alginate microcapsules at the time of transplantation).
- Occurrence of other adverse events or serious adverse events.
- Abnormal laboratory test results, physical examination findings, or ECG findings.
- Psychological impact (as assessed by the ADDQoL quality-of-life questionnaire).
- Clinical and laboratory evidence of xenogeneic infection in transplant recipients via regular monitoring at predefined time points (ongoing).
- Clinical and laboratory evidence of xenogeneic infection in partners/close contacts of the transplant recipients (ongoing).

Primary Efficacy Endpoint

- Reduction in HbA_{1C} levels over the 12-month post-transplant period compared with baseline (week -1).

Secondary efficacy endpoints include:

- Glucose lability assessed using 72-hour continuous glucose monitoring (CGMS[®], Medtronic Minimed, Northridge, CA) at 3, 6 and 12 months post-transplant in comparison with baseline, reported as standard deviation of glucose values at these times (Paty et al. 2006).
- Reductions in hypoglycemia and nocturnal hypoglycemia, as assessed by a composite hypoglycaemic score (HYPO score) over the 12-month post-transplant period compared with baseline (Ryan et al. 2004). Patients will be asked to record the frequency, severity, and degree of unawareness of the hypoglycaemia on a scoring sheet.
- Reductions in the average daily insulin dose of >20% unaccompanied by objective evidence of deterioration of diabetes control at 6 and 12 months post-transplant compared with baseline, as measured by regular 7-point blood glucose profiles and monthly HbA_{1C} levels, in the absence of evidence of major weight loss (>10%) or ketoacidosis.
- Changes in endogenous insulin secretion as determined by the plasma C-peptide response to intravenous glucagon stimulation at 3, 6 and 12 months post-transplant compared with baseline. Pre-transplant this test is expected to confirm a low human C-peptide level; after the xenotransplant, the test should detect porcine C-peptide/insulin.
- Quality-of-life changes, as assessed by the ADDQoL quality-of-life questionnaire (Appendix 2), at 6 and 12 months post-transplant compared with baseline.

An additional clinical trial to test a different dosing regimen is planned to take place in New Zealand later this calendar year.

Scientific papers relating to DiabeCell[®] are available for download on the LCT website at www.lctglobal.com/scientificarticles.php.