



## Living Cell Technologies Limited

### Company Announcement

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#### **LCT Phase II Diabetes Trial Success: Approval to Progress**

- Positive Assessment from NZ Data Safety Monitoring Board and Approval to Progress to next stage of Phase II Diabetes trial with higher dose
- Encouraging data from first four patients on DIABECCELL<sup>®</sup> including elimination of hypoglycaemic unawareness in the first patient treated with no need for immunosuppressant drugs

**30 March 2010: Sydney, Australia & Auckland, New Zealand. Living Cell Technologies Limited (ASX: LCT; OTCQX: LVCLY)**, a global company pioneering the development of a cell implant to treat diabetes, today announced that it has received approval to advance to the next phase of its New Zealand Phase II human clinical trial with its groundbreaking DIABECCELL<sup>®</sup>. The approval follows a positive assessment from the New Zealand Data Safety and Monitoring Board of the first four patients to receive its DIABECCELL<sup>®</sup> implants.

Prof. Bob Elliott, LCT Medical Director said, "We are absolutely delighted that we have been able to demonstrate significantly improved control of blood glucose in this group of patients with difficult to control or unstable diabetes. Using the current smaller dose of DIABECCELL<sup>®</sup>, two patients so far have eliminated or reduced life-threatening episodes of hypoglycaemic unawareness, a serious complication without warning symptoms and which can lead to accidents and coma."

DIABECCELL<sup>®</sup> is LCT's treatment designed to normalise the lives of people with insulin-dependent diabetes. DIABECCELL<sup>®</sup> comprises encapsulated porcine islets (insulin-producing cells) that are implanted into the abdomen of patients using a simple laparoscopic procedure, and work by self-regulating and efficiently secreting insulin in the patient's body. Importantly, LCT's breakthrough proprietary encapsulation technology means that patients receiving DIABECCELL<sup>®</sup> treatment do not require immunosuppressant drugs after implantation. The trial is being conducted by Dr John Baker, Principal Investigator and diabetes specialist based at Middlemore Hospital in Auckland, New Zealand.

Dr Paul Tan, Chief Executive Officer LCT said, "The results reported earlier in the eight-patient Phase I/IIa trial in Russia are now supported by the responses we see in New Zealand patients who have much more unstable diabetes. In the next stage of this New Zealand trial we will be looking to ascertain additional benefits DIABECCELL<sup>®</sup> could deliver with a higher dose."

The first four New Zealand patients were given a single implant of 10,000 islet equivalents/kg body weight (IEQ/kg), the dose similar to that given to some patients in the Phase I/IIa trial in Russia. Patients in the New Zealand trial have unstable diabetes which includes frequent and potentially life threatening episodes of hypoglycaemia. In the first patient treated in NZ, who has been followed for 24 weeks after implant, daily insulin dose has been reduced by 25% and

hypoglycaemic unawareness has been completely eliminated, giving an early indication of success. Further details of all of the trial results will become known once the trial is unblinded on completion.

In the next phase of this trial, four new patients will be given a higher dose of 15,000 IEO/kg, by July 2010 with interim results due in October 2010 and final unblinding and reporting of results after one year follow up. LCT is now investigating the possibilities of conducting additional trials in other jurisdictions.

The protocol for the New Zealand trial of DIABECCELL<sup>®</sup> implants was approved by the NZ Minister of Health in June 2009 following international peer review of LCT's DIABECCELL<sup>®</sup> clinical programme. The protocol requires patients to be monitored for eight weeks before receiving the implant. All recipients of DIABECCELL<sup>®</sup> implants will be followed up intensively for a year and less frequently thereafter. Details of the trial are available at [clinicaltrials.gov/ct2/show/NCT00940173?term=porcine+islets&rank=1](http://clinicaltrials.gov/ct2/show/NCT00940173?term=porcine+islets&rank=1).

Insulin-dependent type I diabetes is caused by the autoimmune destruction of insulin producing cells. Presently, intensive treatment with insulin injections is necessary to normalize blood glucose to prevent future eye, kidney, nervous system and cardiovascular complications. Unfortunately, intensive insulin therapy causes swings in blood glucose levels and life threatening hypoglycaemic unawareness. The latter is a condition when no warning symptoms are felt when blood glucose falls to low levels that can impair consciousness resulting in accidents and coma. ([diabetesnet.com](http://diabetesnet.com) and [diabetesselfmanagement.com](http://diabetesselfmanagement.com)). Hypoglycaemic unawareness is related to the loss of the normal stress response to low blood glucose levels.

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**For further information:** [www.lctglobal.com](http://www.lctglobal.com)

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**About Living Cell Technologies** - [www.lctglobal.com](http://www.lctglobal.com)

Living Cell Technologies (LCT) is developing cell-based products to treat life threatening human diseases. The Company owns a biocertified pig herd that it uses as a source of cells for treating diabetes and neurological disorders. For patients with Type 1 diabetes, the Company transplants microencapsulated islet cells so that near-normal blood glucose levels may be achieved without the need for administration of insulin or at significantly reduced levels. The Company entered clinical trials for its diabetes product in 2007. For the treatment of Parkinson's disease and other neurological disorders, the company transplants microencapsulated choroid plexus cells that deliver

beneficial proteins and neurotrophic factors to the brain. LCT's technology enables healthy living cells to be injected into patients to replace or repair damaged tissue without requiring the use of immunosuppressive drugs to prevent rejection. LCT also offers medical-grade porcine-derived products for the repair and replacement of damaged tissues for research and other purposes.

***LCT Disclaimer***

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