



## **Living Cell Technologies Limited**

### **COMPANY ANNOUNCEMENT**

**Living Cell Technologies Reports Insulin Independence in Two Patients Following Recent Implants of DIABECCELL<sup>®</sup> in Diabetes Clinical Trial 5 May 2009 – Sydney, Australia, Auckland, New Zealand– Living Cell Technologies Limited (ASX: LCT; OTCQX: LVCLY)** today reported that following the latest implants of DIABECCELL<sup>®</sup>, two recipients with long standing insulin dependent diabetes currently do not require insulin injections.

DIABECCELL<sup>®</sup> is LCT's encapsulated insulin-producing porcine pancreatic islet cells.

To date, seven patients with insulin dependent diabetes have received between one and three implants of DIABECCELL<sup>®</sup> without remarkable adverse events in LCT's on-going Phase I/IIa clinical trial.

LCT Medical Director, Professor Bob Elliott, who is in San Diego, USA, delivering a plenary lecture on DIABECCELL<sup>®</sup> at the Annual Meeting of the International Society for Cell Therapy, said, "Having two patients going off their insulin injections gives me tremendous confidence that we have a treatment which can return people with diabetes to a normal life.

All patients followed-up show improvement of diabetes control with better glycated haemoglobin (%HbA1c) levels. I am extremely pleased to see all blood glucose levels in their seven-point recordings to be in the normal range, even with a lower daily dose of insulin."

LCT CEO, Dr Paul Tan added, "The dose escalation and the tightening of the quality specifications of DIABECCELL<sup>®</sup> for the last two implants have led to a very satisfying outcome with the recipients becoming insulin independent and we look forward to an equally positive outcome for future patients. LCT expects DIABECCELL<sup>®</sup> to be established as a product of exceptional commercial value".

#### **Progress Report of DIABECCELL<sup>®</sup> Phase I/IIa Clinical Trial**

- The trial is an open labelled Phase I/IIa investigation to obtain data on the safety and preliminary efficacy of DIABECCELL<sup>®</sup>, encapsulated neonatal porcine pancreatic islets, without the use of immunosuppressive drugs.
- The trial started in Moscow in 2007 and is intended to enrol a total of 10 patients with type 1 diabetes who have given informed consent for their participation. The trial is being monitored by Geny Research Group Inc, a U.S.-based contract research organization.
- To date, seven insulin dependent diabetes patients have been implanted:
  - The trial was designed for Patients #1 - #5 to receive two implants of DIABECCELL<sup>®</sup> at the dose of 5,000 Islet Equivalents per kg body weight (IEQ/kg) at least 6 months apart and for Patients #6 - #10 to receive one implant of 10,000 IEQ/kg.
  - Based on clinical assessment, amendments to the protocol were requested by the investigators to optimise the treatment in this dose-finding study. Patients #3, #4 and #5 received implants of 5,000 and 10,000 IEQ/kg. Patient #2 received a third implant of 10,000 IEQ/kg.

- As summarised in the following Table, patients have been followed up from a minimum of 18 weeks to 96 weeks. Patient #6 failed to attend follow up after 20 weeks and attempts to resume follow-up continue.
- There were no remarkable adverse events following implants of either dose. Repeat implants have been safe to date.
- All patients show improved blood glucose control as reflected by a decrease in their glycated haemoglobin (%HbA1c) level after the implant, apart from Patient #6.
- All blood glucose levels in the seven-point recordings at last follow-up were in the normal range for patients #1, #2, #3, #4, #7. The mean glucose level in all patients is within the range of 5.8 to 8.2 mMol/L. At last follow up, Patient #6 recorded a mean blood glucose of 9.4 mMol/L.
- Two patients, #2 and #7, have both shown an excellent response and do not require exogenously administered insulin.
  - Patient #2 is a 37 year old female with a 15-year history of insulin dependent diabetes. This patient has received two implants of 5,000 IEQ/kg and in February 2009 a third implant of 10,000 IEQ/kg. Prior to the first implant this patient required an average daily insulin dose of 22 units/day. This patient's HbA1c level prior to implant was 8.2% and is currently 7.1%, her current mean blood glucose level is normal at 6.8 mMol/L.
  - Patient #7 is a 63 year old male with a 5-year history of insulin dependent diabetes. He received one implant at the dose of 10,000 IEQ/kg in January 2009. Prior to implant this patient required an average daily insulin dose of 37 units/day. This patient's HbA1c level prior to implant was 8.3% and is currently 4.8%, his current mean blood glucose level is normal at 6.6 mMol/L
- As previously reported, capsules containing viable cells have been retrieved from second implants and porcine insulin has been detected in blood of patients following glucose tolerance test
- The body weight of all patients during the study varied by less than 5% of their pre-implant weight.

Table: Preliminary Efficacy Response Data

Patient No.	No. of Implants	Follow-up (Weeks)	Insulin Dose (Units/day)		% Dose Reduction	HbA1c (%)		Current Mean Glucose (mMol/L)
			Pre-Implant	Current		Pre-Implant	Current	
1	2	96	113	76	33	7.1	6.1	6.9
2	3	84	22	<b>0</b>	<b>100</b>	8.2	7.1	6.8
3	2	72	60	53	12	10.0	7.4	7.3
4	2	60	30	27	10	7.6	6.5	5.8
5	2	30	68	48	29	9.8	7.2	8.2
6*	1	20*	41	57*	-	8.5	8.5*	9.4*
7	1	18	37	<b>0</b>	<b>100</b>	8.3	4.8	6.6

\* Patient lost to follow-up (data\* at 20 weeks follow-up)

**Summary: The Phase I/II dose escalation trial to date has implanted seven insulin dependent diabetes patients with one to three implants of DIABECCELL<sup>®</sup> without remarkable adverse events. Preliminary efficacy data show normalised blood glucose levels and improved HbA1c with reduction of daily insulin dose. Two recipients have discontinued insulin injections.**



**Presentation by Professor Bob Elliott**

Title: Practical, Methodological, Regulatory Aspects of Islet Cell Implants – DIABECCELL®.  
International Society for Cell Therapy 15<sup>th</sup> Annual Meeting  
5<sup>th</sup> May 2009 at 1:30 -3:00 pm US Pacific Time  
Sheraton, San Diego, CA, USA

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**For further information:**

Dr. Paul Tan  
Chief Executive Officer  
Mob:+64 21 608 784  
Tel: +64 9 2762690  
[ptan@lctglobal.com](mailto:ptan@lctglobal.com)

Mr John Cowan  
Finance & Administration Manager  
Tel: +64 9 276 2690  
[jcowan@lctglobal.com](mailto:jcowan@lctglobal.com)

Prof. Bob Elliott  
Medical Director  
Mob: +64 27 292 4177  
Tel:+64 9 276 2690  
[belliott@lctglobal.com](mailto:belliott@lctglobal.com)

Rebecca Wilson  
Investor and Media Relations  
Mob: +61 417 382 391  
Tel: +61 3 9866 4722  
[rwilson@bcg.com.au](mailto:rwilson@bcg.com.au)

**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 Parkinson's disease, Huntington's disease and other neurological disorders, the company is developing 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, as well as for research and other purposes.*

**LCT Disclaimer**

This document contains certain forward-looking statements, relating to LCT's business, which can be identified by the use of forward-looking terminology such as "promising," "plans," "anticipated," "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to," "potential," "seeking to," "goal," "could provide," "intends," "is being developed," "could be," "on track," or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA's and other health authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any health authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialisation of the product candidates could be affected by, among other things, unexpected clinical trial results, including additional analysis of existing clinical data, and new clinical data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. LCT is providing this information as of May 2009 and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.