



## Living Cell Technologies Limited Company Announcement

### LCT Presents at IPITA World Congress in Prague

**6 June 2011: Sydney, Australia & Auckland, New Zealand. Living Cell Technologies Limited (ASX: LCT; OTCQX: LVCLY)**, a global company pioneering the development of cell implants to treat diabetes, today announced that key findings from DIABECCELL<sup>®</sup> Phase II New Zealand clinical data were presented at the 13th World Congress of IPITA, the International Pancreas and Islet Transplant Association, held 1-4 June 2011, Prague, Czech Republic by Professor Robert Elliott, Medical Director of LCT and Dr Olga Garkavenko, director of LCT Research and Development.

The International Pancreas and Islet Transplant Association is a scientific forum for the exchange and discussion of clinical and experimental results and experiences relevant to transplantation of insulin producing tissue in the treatment and cure of diabetes mellitus.

LCT's lead product, DIABECCELL, comprises encapsulated neonatal pancreatic islets that are implanted into the abdomen of patients using a simple laparoscopic procedure. Professor Elliott's presentation is entitled "Microencapsulated neonatal porcine islet implants alleviate unaware hypoglycaemia without immune suppression".

Professor Elliott presented data that showed a dramatic reduction in severe and unaware hypoglycaemia after low dose islet xenotransplantation procedure without immune suppression, despite only modest reduction in insulin dose. This benefit could be related to the post implant hormonal changes measured.

Dr Garkavenko also gave an oral presentation at the conference entitled "Managing potential zoonotic infections in swine-to-human islet xenotransplants". Dr Garkavenko presented information on a key safety aspect of LCT's xenotransplantation project.

LCT has 14 years of experience in developing and implementing a comprehensive xenosafety program that includes two aspects; donors' microbiology evaluation and recipients' follow-up. This program has its particular focus on potential pig endogenous retrovirus infection. Multiple in-depth screenings of the donors before transplantation for the functional virus assure the minimal risk of its transmission as the result of xenotransplantation. The same rigorous approach is applied for other pig viruses relevant to xenotransplantation. LCT is reporting that to date the follow-up of its 27 patients treated with pig islet cells shows no evidence of PERV or other pig viruses transmission.

Dr Garkavenko is also scheduled to speak at the Berlin Symposium on Xenotransplantation, hosted by DFG-Transregio Research Group Xenotransplantation together with the 14th Minisymposium Xenotransplantation of the German Working Group Xenotransplantation (DAX), on 9 June 2011, 9:30 am at the Robert Koch Institute, in Berlin Germany. Dr Garkavenko's

presentation is entitled "The first clinical xenotransplantation trial in New Zealand: efficacy and safety."

DIABECELL has recently completed the treatment phase of its Phase II dose-seeking clinical trial in New Zealand, and has announced approval to begin a clinical trial in Argentina.

"We are pleased to be sharing our latest findings with key opinion leaders in this field. Our data supports the long term safety of DIABECELL and dramatic efficacy in improving the management of patients suffering from a life threatening complication of Type 1 diabetes. As the monitoring phase from our trial continues, we will continue to gather critical information and understanding about our treatment," said Professor Bob Elliott, LCT Medical Director.

Professor Elliott's and Dr Garkavenko's complete IPITA presentations are appended.

### Presentation Abstract

#### Microencapsulated Neonatal Porcine Islet Implants Alleviate Unaware Hypoglycaemia without Immune Suppression

R.B. Elliott, on behalf of Living Cell Technologies, Prague, June 2011

**Aims:** Unaware hypoglycaemia occurs in up to 20% of Type 1 diabetics and may be responsible for 8% of deaths in this group. It has been shown previously that even partial restoration of insulin production by human islet intra-hepatic transplantation with immune-suppression can restore awareness. We describe the effects of porcine islet implantation without immune-suppression on this important iatrogenic complication of the disease.

**Methods:** Alginate/polyornithine/alginate microencapsulated neonatal porcine islets were implanted into the peritoneal cavity of 14 adult Type 1 diabetic patients with unstable diabetes, after a two month pre-implant intensified treatment and observation. The trial was approved by the relevant ethical and scientific bodies in New Zealand. The dose of islets was escalated from 5,000/kg to 20,000/kg.

Diabetes control was assessed by 7/day blood glucose determinations with intermittent periods of continuous glucose monitoring, as well as HbA1c measurements and a standardized record of hypoglycaemic episodes. Daily insulin requirements were recorded as daily average/week. Insulin was measured by a validated quantitative HPLC method specific for porcine insulin. In addition pre and post transplant counter-regulatory hormonal responses to a standardized insulin induced hypoglycaemic episode were measured.

**Results:** The average results to date over the first year are shown for the lower dosed patients are shown in the Table. Most notable is the dramatic reduction in unaware hypoglycaemia despite only modest reduction in insulin dose and little change in high blood glucose related data.

Parameter	Pre-Tx	Post-Tx	
		Up to Week 12	Up to Week 12-52
Insulin Dose (Weekly Average)	41	36	30
Hypo Score (Weekly Average - Severity Indicator)	20	12	8
Number of Unaware Hypos (Weekly Average)	3.2	1.5	0.8

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The higher islet doses are somewhat less effective in these regards. This paradoxical finding had been seen previously in two animal models.

Improvement in the defective glucagon and adrenergic responses to hypoglycaemia was seen in the group.

No significant adverse events were encountered except in one individual receiving the highest dose of encapsulated islets who presented with a transient possible allergic reaction 7-10 days after implantation.

Conclusions: This low dose islet xenotransplantation procedure without immune suppression appears to be effective in alleviating severe and unaware hypoglycaemia., despite only modest reduction in insulin dose. This benefit could be related to the post implant hormonal changes measured.

– Ends –

**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 implants its lead product DIABECCELL, microencapsulated islet cells, in an effort to address the shortcomings of existing insulin therapy. 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, NTCELL, which delivers beneficial proteins and neurotrophic factors to the brain. LCT's breakthrough microencapsulation technology, IMMUPEL™, 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**

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*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 commercialization 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 materialize, 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 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.*