



## Living Cell Technologies Limited

### Company Announcement

#### Report from LCT's Russian Phase I/IIa Diabetes Trial

### Living Cell Technologies Confirms Safety and Proof of Principle of Efficacy in its Penultimate Data Analysis from its Russian Human Phase I/IIa Trial with DIABECCELL<sup>®</sup> in Diabetics

- *DIABECCELL<sup>®</sup> Successfully Meets End Points for Safety and Tolerability; Shows Proof of Principle of Efficacy in Humans with Insulin-dependent (Type 1) Diabetes*
- *Results Accepted for Oral Presentation at Scientific Meeting of American Diabetes Association*

**7 April 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 provided a penultimate update regarding the three-year follow up of its Phase I/IIa clinical trial in Russia of its DIABECCELL<sup>®</sup> treatment in insulin-dependent diabetics. The data analysis has confirmed that the trial has successfully met its end points of demonstrating safety and tolerability. In addition, the groundbreaking treatment has shown proof of principle of efficacy in humans with insulin-dependent (Type 1) diabetes. These results have been accepted for oral presentation at the scientific meeting of the American Diabetes Association in June. These positive data, taken together with positive progress in LCT's Phase II trial in New Zealand, provide encouragement to progress DIABECCELL<sup>®</sup> further towards commercialisation.

Prof. Bob Elliott, LCT Medical Director said, "We are pleased that our treatment has shown so far to be safe and well tolerated. We are encouraged that we have demonstrated that DIABECCELL<sup>®</sup> may be safely administered up to three times and that we have seen evidence of continuing efficacy exemplified by the patients clearly showing reduced HbA1c levels as well as the daily dose of insulin injections, with better control over their blood glucose levels. Patients volunteered that they sensed greater well being."

DIABECCELL<sup>®</sup> is LCT's treatment designed to normalise the lives of people with insulin-dependent diabetes. DIABECCELL<sup>®</sup> comprises encapsulated porcine insulin-producing cells (islets) 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. LCT's breakthrough proprietary encapsulation technology means that patients receiving DIABECCELL<sup>®</sup> treatment do not require immunosuppressant drugs after implantation.

Prof. Boris Draznin, Director of the Adult Diabetes Program at University of Colorado Denver, School of Medicine, who has long followed islet transplantation, said, "This is the first time that



anyone with long term insulin-dependent diabetes has come off insulin injections following islet cell implants without using immunosuppressant drugs."

The trial, which commenced in June 2007 is reported for the eight patients. The patients, between 21 and 68 years of age with insulin-dependent diabetes have received between one and three implants of DIABECCELL<sup>®</sup> with only minor adverse events. Blood samples taken from patients over the past 34 months have tested negative for any pig-to-human transmission of diseases. Six of the eight patients have shown improvements in blood glucose control as reflected by reduction in glycated haemoglobin (HbA1c %) levels and reduction of the required daily dose of insulin injections. Two patients discontinued insulin injections entirely; the longest period was for a span of 14 weeks. The trial was conducted in the Sklifosovsky Institute Moscow.

All trial patients will continue to be monitored to establish the duration of clinical benefit and safety. LCT is investigating the possibilities of conducting additional trials in other jurisdictions. LCT also recently reported that DIABECCELL<sup>®</sup> has also progressed to the next stage if its Phase II studies in New Zealand having received approval from the New Zealand Data Safety and Monitoring Board in late March to advance to implants at higher doses.

Dr Paul Tan, Chief Executive Officer for LCT, said, "We are pleased with the progress we are making with DIABECCELL<sup>®</sup> in our trials in Russia and New Zealand. Our Phase II trial in New Zealand will help us to determine the optimum dosing regimen. We are thus pleased to be making positive progress towards commercialisation."

**See Appendix for further details**

*- Ends -*

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

<b>At the company:</b>	<b>Media and investor enquiries:</b>
<p>Dr. Paul Tan Chief Executive Officer Mob: 021 608 784 (NZ) Tel: +64 9 276 2690 <a href="mailto:ptan@lctglobal.com">ptan@lctglobal.com</a></p> <p>Mr John Cowan Finance &amp; Administration Manager Tel: +64 9 276 2690 <a href="mailto:jcowan@lctglobal.com">jcowan@lctglobal.com</a></p> <p>Prof. Bob Elliott Medical Director Mob: +64 27 292 4177 Tel: +64 9 276 2690 <a href="mailto:belliott@lctglobal.com">belliott@lctglobal.com</a></p>	<p>International enquiries: College Hill - <a href="mailto:lct@collegehill.com">lct@collegehill.com</a></p> <p>US: Erik Clausen / Rebecca Skye Dietrich Mob: +1 781 608 7091 Tel: +1 415 230 5385</p> <p>Europe: Sue Charles / Justine Lamond Mob: +44 7968 726585 Tel: +44_20 7457 2020</p> <p>NZ and Australia: Buchan Consulting Paul Dekkers Tel: +612 9237 2800 <a href="mailto:pdekkers@bcg.com.au">pdekkers@bcg.com.au</a></p>

**APPENDIX  
MARCH 2010 SUMMARY RUSSIAN CLINICAL TRIAL**

**LCT/DIA-07R STUDY DESIGN**

Eight patients with Type 1 Diabetes Mellitus between the ages of 21 and 65 years inclusive, who were eligible for the study, received the following doses of DIABECCELL<sup>®</sup> via laparoscopic implant into the peritoneal cavity.

Table 1: Dose of implants

Patient ID	1 <sup>st</sup> Implant (IEQ/kg)	2 <sup>nd</sup> Implant (IEQ/kg)	3 <sup>rd</sup> Implant (IEQ/kg)
001	5,000	5,000	10,000
002	5,000	5,000	10,000
003	5,000	10,000	10,000
004	5,000	10,000	10,000
005	5,000	10,000	N/A
006	10,000	N/A	N/A
007	10,000	10,000	N/A
008	10,000	N/A	N/A

Patients received 5,000 or 10,000 IEQ per kg body weight. Repeat implants were administered as shown in the preceding Table and scheduled at least 6 months apart.

**RESULTS**

8 patients have been followed up for safety evaluation for a period of up to 18 months post receipt of their first implant of DIABECCELL<sup>®</sup>.

Patients have been followed up for efficacy evaluation for varying periods up to 24 months post receipt of their first implant of DIABECCELL<sup>®</sup>.

Parameters used to evaluate efficacy of DIABECCELL<sup>®</sup> implants include daily insulin dose requirements and blood HbA1c (%) levels.

***With regard to safety:***

- There were no significant adverse events reported following either single implants or repeat implants of DIABECCELL<sup>®</sup>
- 2 patients reported adverse events of abdominal discomfort occurring up to 5 days post implant, although both of these patients fully recovered without experiencing any residual effects
- To date all results from the analyses of patient samples for PERV RNA and PERV DNA have been negative



***With regard to efficacy as demonstrated by reduction of HbA1c (%) levels and daily insulin dose requirements when compared to those requirements prior to the patient receiving their first implant of DIABECCELL® :***

- At 6-months follow-up post first implant, 6 of the eight 8 patients demonstrated HbA1c (%) levels which were reduced by a range between 0.2 and 2.8 % units. The 6 patients demonstrated a reduced requirement for daily insulin dose of between 13% and 100%, the insulin requirement for one of these patients was reduced by 100% at 3-months post first implant and by 32% at 6-months post first implant.
- At 12-months follow-up post first implant (6-months follow-up post second implant) all 5 patients demonstrated HbA1c (%) levels which were reduced by a range between 0.5 and 2.1 % units. All 5 patients demonstrated a reduced requirement for daily insulin dose which ranged between 10% and 25%
- At 15-months follow-up post first implant (3-months follow-up post third implant) all 4 patients demonstrated HbA1c (%) levels which were reduced by a range between 0.2 and 1.7 % units. All 4 patients demonstrated a reduced requirement for daily insulin dose which ranged between 10% and 100%
- At 18-months follow-up post first implant (6-months follow-up post third implant) 2 of the 3 patients demonstrated HbA1c (%) levels which were reduced by a range between 0.9 and 1.3 % units respectively. All 3 patients demonstrated a reduced requirement for daily insulin dose which ranged between 10% and 100%
- At 24-months follow-up post first implant (12-months follow-up post third implant), one patient has reached this stage of follow-up and demonstrated a reduced requirement for daily insulin dose of 82%
- In total, 2 of the 8 patients implanted became insulin independent for 4 weeks and 32 weeks respectively
- At the time of repeat implants, intact capsules were retrieved and shown to contain viable islets. Porcine insulin was also detected in the patient's blood following challenge with a Sustacal meal.

**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 bio-certified 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 immunosuppressant 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 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.*