Living Cell Technologies Ltd

COMPANY ANNOUNCEMENT

Living Cell Technologies Announces Compelling Interim Diabetes Trial Results

March 31, 2008, Melbourne, Australia and Auckland, New Zealand. Living Cell Technologies Limited (ASX:LCT; OTC: LVCLY.PK) today announced new positive 6 month interim results from the Phase I/IIa clinical trial of DiabeCell® for the treatment of type 1 diabetes at the International Diabetes Federation (IDF) Congress in Wellington, New Zealand and the NZBio Conference in Auckland, New Zealand.

Professor Bob Elliott, Medical Director of LCT at the IDF Congress and Dr. Paul Tan, CEO, at the NZBio Conference, reported that four insulin dependent patients have received DiabeCell® implants with no remarkable adverse events. Two of the patients have completed 6 months observation and maintained significant prolonged clinical benefit.

"Early results from the trial of DiabeCell® at the lowest dose believed to produce measurable outcomes, have demonstrated that DiabeCell® was functional at 6 months, and that implantation significantly reduced the need for additional administration of insulin more than the anticipated maximum of 25%," said Professor Elliott.

"There is no doubt that a reduction in the level of exogenously administered insulin is beneficial to people with type 1 diabetes. The preliminary results are early and unlike adult islets, neonatal islets take time to mature and delayed benefit can still be expected."

Professor Elliott continued "These remarkable clinical outcomes have exceeded our expectations. We expect that higher doses of DiabeCell® will support greater reductions in the insulin needs of patients."

Summary of 6 Month Follow-up Results

- Four type 1 diabetes patients have been implanted according to the approved trial protocol with a low dose of DiabeCell® and one of the four has received a scheduled second implant six months after the initial implant.
- The first two patients have shown significantly reduced need for exogenously administered insulin. One male patient's daily insulin requirement was reduced by 40% over a 6-month period, and a female patient's need for exogenous insulin was reduced 100% during a 5–month period before she resumed daily insulin on medical advice to attain better blood glucose control and insulin dosage reduction of 82% was maintained at 6 months follow up.
- Implanted microencapsulated cells retrieved from a patient at the time of the second implant showed that the microencapsulated cells were intact and contained viable cells. There was no evidence of capsule damage by the immune system, even though no immunosuppressive drugs were administered in the DiabeCell® protocol in contrast with the need for immunosuppression when human islet cells are transplanted using the Edmonton protocol.
- At 12 weeks after the second implant the daily insulin requirement was maintained at 40 - 47% of the pre-implant requirement with stable glucose control.
- The third patient required an increased daily dose of insulin soon after the first implant to cope with a stressful personal social problem unrelated to the implant procedure. This patient has not completed 6 months follow-up and insulin requirement was unchanged at 8 weeks post implant.

- The fourth patient received her first implant in February 2008 and her daily insulin requirement was reduced by 10% at only 4 weeks post implant.
- Results from the first tests for potential porcine endogenous retroviral infections were negative for all 4 implant recipients

About the trial

- The trial is under way in Moscow and is intended to enroll a total of six patients having type 1 diabetes who have given informed consent for their participation
- The trial is being monitored by a U.S.-based contract research organization (CRO)
- Patients receive one implantation of DiabeCell® at the lowest dose anticipated to demonstrate a measureable improvement in glucose control and need for insulin (among other parameters) at the commencement of the treatment and again following an additional implant six months later
- The following parameters are being measured pre- and post-implant:
    - Daily insulin dose
    - Continuous glucose monitoring
    - Haemoglobin A1c (to indicate average blood glucose over a two-month period)
    - C-peptide in blood (a measure of insulin production) after a standard stimulus
    - Frequency of episodes of low blood glucose
    - Patient satisfaction

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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. Updated Protocol LCT/DIA-07R.

Trial centre details:

- Sklifosovsky 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 Organization

Clinical Trial Protocol:

As of 31 March 2008, 6th month follow-up interim report of evaluable data:

Four adult subjects have received implants and one had had a second implant.

- The human clinical trial of DiabeCell® in Russia has approval to include six Type 1 (insulin-dependent) diabetics in two stages. Subjects are over 21 years old to 65 years of age. The candidates have had type 1 diabetes for at least 5 years with no other complications and provide full consent for follow-up monitoring. The patients received 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 was equivalent to 5,000 IEQ

(islet equivalents/kg). The second transplant was a further 5,000 IEQ's. The procedure was minimally invasive and administered into the abdomen through a laparoscope.

Primary Safety Endpoints

- One patient had a transient fever following the first implant.
- Two patients had transient non-specific upper respiratory symptoms one at 2 weeks and the other at 12 weeks after the first implant.
- No perioperative reactions were reported. Laparoscopic examination at the second implant in one patient showed no local tissue reactions to implanted microcapsules
- Results from the first tests for porcine endogenous retroviral infections are negative in all implant recipients

Report on Endpoints to follow are:

- 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

For two patients completing 6 months follow-up, insulin requirement was adjusted over the 6-month post-transplant period to maintain control of glucose metabolism at or below the target of HbA1c at 7%.

Secondary efficacy endpoints include:

For both patients completing 6 month follow-up the reduction in average daily insulin requirement exceeded expectation of 25% for the first dose and was at least 40% and 75% and this was maintained.

Report on Endpoints to follow are:

- 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 >25% 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 (>10T) or ketoacidosis.
- Changes in endogenous insulin secretion as determined by the plasma C-peptide response to a Sustacal Meal 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.

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

About Living Cell Technologies: www.lctglobal.com

Living Cell 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 .having type 1 diabetes, the Company implants micro-encapsulated 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. The Company is developing treatments for Huntington's disease and other neurological disorders that involve implantation of micro-encapsulated choroid plexus cells to deliver beneficial proteins and neurotrophic factors to the brain. Living Cell's technology has the potential for allowing healthy living cells to be injected into patients to replace or repair damaged tissue without requiring the use of immunosuppressive drugs to prevent rejection. Living Cell also is developing medical-grade porcine-derived products for the repair and replacement of damaged tissues, as well as for research and other purposes. The changes in this paragraph reflect that the company only is developing or might develop certain products, and is not manufacturing or selling any products other than DiabeCell

LCT Disclaimer

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