Living Cell Technologies Ltd

COMPANY ANNOUNCEMENT

Living Cell Technologies Reports Clinical Benefit for All Patients in Diabetes Trial

July 22, 2008, Melbourne, Australia and Auckland, New Zealand. Living Cell Technologies Limited (ASX:LCT; OTCQX: LVCLY) today released further interim results describing clinical benefit in all patients who have received implants of DiabeCell®, the Company's encapsulated porcine islet cells for the treatment of type 1 diabetes.

Six patients with insulin dependent diabetes have now received DiabeCell® implants. Five patients in the first group received the lowest dose of 5,000 islet equivalents (IEQ/kg) and two of them have received a second implant of the same dose. To date, no remarkable adverse events have occurred during the trial, which has enabled LCT to meet clinical milestones in relation to safety for up to 12 months follow up.

The trial has been expanded to a second group of five patients and the sixth patient in the trial has been implanted with the higher dose of 10,000 IEQ/kg.

Professor Elliott, LCT Medical Director said, "At this stage in the DiabeCell® trial clinical benefit has been observed in all five patients receiving the lowest dose which has far exceeded our expectations. In the first group, following DiabeCell® implants we have seen reductions in daily insulin requirements ranging from 23% to as much as 100% while maintaining good control of blood glucose levels in four out of five patients".

"In patients who have had the longest follow-up period, we have seen reductions in insulin requirements of 24% and 54% being maintained at 12 and 11 months in the first two subjects respectively. We have also reported the detection of porcine insulin in blood samples of patients confirming that the implanted islets remained functional at 6 months and 11 months after the first implant."

Improvement in blood glucose control in the group is reflected by the Mean glycated hemoglobin (HbA1c) level which fell from 8.5% pre-implant to 6.8% at the time of last measurement

The lowest patient response was a 10% maximum reduction in daily insulin requirement. The patient's HbA1c dropped markedly however, from 10.1 to 7.3 following the implant. This result indicates better blood glucose control after treatment with DiabeCell® and continuous glucose monitoring has confirmed this.

"The swings in blood glucose levels and his diabetes control have improved dramatically not with more but with a smaller insulin dose and the lowest dose of DiabeCell®." said Professor Elliott.

"The magnitude and duration of clinical responses observed with the lowest dose leads us to expect that higher doses of DiabeCell® will support greater and longer term reductions in the insulin needs of patients."

Dr Paul Tan, LCT CEO, said, "The positive clinical results have prompted us to expand our pig breeding facilities to meet supplies of DiabeCell® for advancing our clinical and commercial programs internationally."

About the trial

- The trial is under way in Moscow and is intended to enroll a total of ten 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)
    - Porcine insulin in blood after a standard stimulus
    - Frequency of episodes of low blood glucose
    - Patient satisfaction

See APPENDIX for further details

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APPENDIX:

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.

Protocols: LCT/DIA-07R and LCT/DIA-07R2

Trial Centre Details:

- Site: Sklifosovsky Institute
- CRO: Monitoring by Contract Research Organization , Geny Research Group (US)

Clinical Trial Protocol:

Interim report of evaluable data as of 15 July 2008:

Six adult subjects have received implants and two have had a second implant.

- The human clinical trial of DiabeCell® in Russia has approval to include 10 patients with Type 1 (insulin-dependent) diabetes. 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. In the first group, five patients received an initial implant (a simple injection of encapsulated islets into the peritoneal cavity of the patient) followed by a second implant six months later. The first implant dose was equivalent to 5,000 IEQ (islet equivalents/kg). The second transplant was a further 5,000 IEQ/kg. The procedure was minimally invasive and administered into the abdomen through a laparoscope.
  In the second group, five more patients are to receive 10,000IEQ/kg

Table 1: Patient demographics, implants received and adverse events

Patient ID	Age	Sex	Disease Duration (Years)	DiabeCell® Implants	Follow-Up (Months)	Adverse Events Attributable to Trial Procedure
1	25	M	10	5,000 IEQ x2	12	Fever 38°C for 3 days at 1 week post first implant
2	38	F	15	5,000 IEQ x2	10	Nil
3	23	M	5	5,000 IEQ x1	5	Nil
4	36	F	7	5,000 IEQ x1	4	Nil
5	29	M	5	5,000 IEQ x1	1	Nil
6	23	M	6	10,000 IEQ x1	-	Nil

Note: All Patients were treated with an insulin pump except Patient#4

Primary Safety Endpoints

There were no remarkable adverse events.

- 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 remarkable perio-perative reactions were reported.
- There have been no episodes before or after the implants meeting the criteria for hypoglycaemic state
- 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

Insulin requirement was adjusted over the post-transplant period to maintain control of blood glucose levels and attain a targeted level of glycated haemoglobin [HbA1c] at or below 7%. **Mean HbA1c fell from 8.5% pre-implant to 6.8% at last measurement.** Reductions in HbA1c associated with reductions in daily insulin requirement, were noted in 4 of 5 patients (Table 2). In one patient, the HbA1c increased from 7.3% to 7.6% during a 4 month post-implant follow-up period.

Table 2: Primary Outcome: Reduction in HbA1c

Patient ID	HbA1c %		Post-Implant Follow-Up (Months)
	Pre-Implant	Post-Implant	
1	7.1	6.9	11
2	8.2	6.5	10
3	10.1	7.3	5
4	7.3	7.6	4
5	9.8	5.6	3

Table 3: Reduction in Insulin Dose

Patient ID	Pre –Implant		Post-Implant (Follow-Up in Months after First Implant)		
	Weight (Kg)	Average Insulin Dose (Units/Day)	Maximum % Reduction in Insulin Dose	Current % Reduction in Insulin Dose	Weight Kg
1	108	111	46 (8m)	24 (11m)	101 (9m)
2	66	23	100 (1m)	54 (12m)	65(10m)
3	90	60	10 (1m)	8 (5m)	94 (5m)
4	67	30	29 (2m)	10 (4m)	64 (4m)
5	110	78	23 (2m)	23 (2m)	108 (1m)

Secondary Efficacy Endpoints:

Reduction in daily insulin dose was noted in all patients as summarized in Table 3 with the average maximum reduction of 41.6% (range 10% -100%) for the group at the current stage of the study. The accompanying current HbA1c ranged from 5.6% to 7.6%. For the same period of observations, none of the patients registered a change of body weight of >10%.

The reduction in average daily insulin dose requirement was greater than 23% (range 23% -100%) in four of five patients. One patient (Patient ID# 3) had a maximum reduction in daily insulin dose of 10% only but this was accompanied by a large fall of HbA1c from 10.1% to 7.3% indicating significant improvement in glycaemic control. This was confirmed by the continuous glucose monitoring device recording significant reduction in the amplitude of blood glucose excursions (Mean Amplitude of Glycaemic Excursion to be reported in detail)

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 (>10%) or ketoacidosis.
- Changes in endogenous insulin secretion as determined by the plasma porcine insulin response response to a Sustacal Meal at 3, 6 and 12 months post-transplant.
- Quality of life changes, as assessed by the ADDQoL quality-of-life questionnaire, at 6 and 12 months post-transplant compared with baseline.

Interim Summary and Conclusions

- Preliminary data shows that following DiabeCell® implantation, clinical benefit was noted in all 5 patients in the first group who have been implanted with the lowest dose of 5,000 IEQ/kg DiabeCell®
- In four of the five patients, control of blood glucose levels improved as reflected by the fall in HbA1c. The mean HbA1c for the group fell from 8.5% to 6.8%. In the patient whose HbA1c did not improve, the average daily dose of insulin required was reduced by a maximum of 29 %.
- The maximum reduction in daily insulin dose for the five patients ranged from 10% - 100% (mean 41.6%). In the patient with only 10 % reduction in daily insulin dose, control of blood glucose levels improved markedly as reflected by the fall in HbA1c.
- Porcine insulin was detected in blood samples from the first two patients confirming that the implant remained functioning at 6 months and 11 months following the first implant

- There were no remarkable adverse events following implantation of the lowest dose and the trial has been expanded to a further 5 patients who are to be administered the higher dose of 10,000 IEQ/kg. The sixth patient in the trial has been implanted with the higher dose.

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.

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