



## Living Cell Technologies Limited

**CAN:** 104 028 042  
**ASX:** LCT  
**OTCQX:** LVCLY

### ASX ANNOUNCEMENT

## Safety and efficacy findings of DIA-09 study of DIABECCELL for type 1 diabetes

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**31 October 2013 – Sydney, Australia & Auckland, New Zealand** – Living Cell Technologies Limited today announced the findings of DIA-09 - a Phase I/IIa clinical trial of DIABECCELL® in patients with type 1 diabetes.

The non-randomised, open label, study was conducted at the Hospital Eva Perón, Buenos Aires, Argentina by Principal Investigator - Dr. Adrián G. Abalovich.

The trial involved eight patients split into two groups of four. Group one received two 5,000 IEQ/kg doses of DIABECCELL (islet equivalents per kilogram of body weight). Group two received two 10,000 IEQ/kg doses of DIABECCELL. In both groups, the second dose was implanted 12 weeks after the first. Endpoints were assessed 52 weeks after the second implant.

The main findings one year after the second implant are:

- Overall unaware hypoglycaemic events (UHE) were reduced by 57%. All patients (4/4) in the higher dose group reduced UHE by >40% without an increase in HbA1c and 3 of 4 patients in the lower dose group reduced UHE by >30% without an increase in HbA1c.
- HbA1c fell 1.5-2% in the group receiving the bigger dose and 3 of 4 patients in this group maintained HbA1c of <7%
- The average daily insulin dose was reduced in 7/8 patients.
- Modified Ryan scores indicating the frequency and severity of hypoglycaemic events were significantly reduced in the higher dose group

Analyses are underway to measure levels of porcine insulin and pro-insulin in recipients and correlate these with the clinical improvements observed.

All participants had minor side effects from the implantation of DIABECCELL, such as abdominal pain and fever, and these quickly resolved. One recipient had a severe adverse event from the implantation, namely lack of bowel movement, and this settled with intravenous medication.

Managing Director, Andrea Grant says, "Just as one would hope for with a Phase I/IIa study, these results provide invaluable safety and efficacy data as the basis for further improvements in the product and its method of administration. As previously announced, recent research and development work performed by Diatranz Otsuka Limited (DOL) indicates that there is a genuine opportunity to develop an improved formulation of DIABECCELL and a revised regulatory pathway for this improved formulation is currently in preparation"

The results have been accepted for presentation at the 12<sup>th</sup> Congress of the International Xenotransplantation Society being held in Osaka, 10<sup>th</sup> – 13<sup>th</sup> November, 2013.

– Ends –

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

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## About DIABECCELL

Diabetes is usually treated with insulin replacement. A serious and potentially fatal complication associated with intensive insulin replacement therapy is unaware hypoglycaemia. Episodes of unaware hypoglycaemia occur when, without associated symptoms or warning, blood glucose levels drop suddenly. Some patients require significant time and resources from specialist healthcare professionals and have a poor prognosis: lower quality of life, more micro vascular and pregnancy complications and shortened life expectancy.

Treatment with DIABECCELL™ involves transplanting pig pancreatic islet cells into a patient's abdomen to boost insulin production and help regulate blood glucose levels. The cells are encapsulated with IMMUPEL™ to prevent the immune system rejecting them as foreign. This proprietary technology ensures the cells can deliver their beneficial effects without the patient requiring immunosuppressant drugs.

DIABECCELL is owned by the joint venture company Diatranz Otsuka Limited, in which LCT and Otsuka Pharmaceutical Factory both have a 50% interest.

## About Living Cell Technologies

Living Cell Technologies (LCT) is an Australasian biotechnology company and world leader in developing cell therapies to treat diseases with high unmet clinical need. To date, the company has taken two therapeutic candidates into clinical development: DIABECCELL®, for the treatment of Type 1 diabetes and NTCELL®, which is in Phase I clinical trials in New Zealand for the treatment of Parkinson's disease.

Through an innovative joint venture, Diatranz Otsuka Limited (DOL) with international pharmaceutical company Otsuka Pharmaceutical Factory (OPF), LCT has secured funding, based on the achievement of clinical milestones, for the clinical development of DIABECCELL and the Phase I clinical trials of NTCELL in Parkinson's disease. LCT retains a 50% share of future profits from DIABECCELL and NTCELL and a perpetual, exclusive licence to continue to develop products using intellectual property held outside the DOL partnership.

LCT's unique, proprietary technology, IMMUPEL™, allows cell therapies to be used without the need for co-treatment with drugs that suppress the immune system, which often have negative side-effects.

LCT is listed on the Australian (ASX: LCT) and US (OTCQX: LVCLY) stock exchanges. The company is incorporated in Australia, with its research and development, operations and manufacturing facilities based in New Zealand.

For more information visit [www.lctglobal.com](http://www.lctglobal.com) or follow @lctglobal on Twitter

## **LCT disclaimer**

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