



## Living Cell Technologies Limited

### Company Announcement

## LCT starts DIABECCELL<sup>®</sup> Phase IIb trial in Argentina

**Date: 22 November 2012 Sydney, Australia and Auckland, New Zealand** – Living Cell Technologies Limited (ASX: LCT; OTCQX: LVCLY) has begun patient recruitment in Argentina for a Phase IIb trial of DIABECCELL.

The trial is designed to demonstrate the clinical benefits of DIABECCELL in unstable type 1 diabetes. Twenty patients will receive two implants of 10,000 IEQ/kg (islet equivalents per kilogram of body weight), with the second implant occurring 12 weeks after the first. This is the dose which was shown to be most clinically effective in reducing HbA1c, insulin dose and unaware hypoglycaemic events in the recently announced interim analysis of the Phase I/IIa trial in Argentina.

The principal investigator of the Phase IIb trial is Dr Adrián Abalovich of Hospital Eva Perón in San Martín, Buenos Aires.

“We are using an ‘adaptive trial design’ for our pivotal studies and so the data generated in this 20 patient trial will likely form the foundation data for our registration package,” said Dr Andrea Grant, Chief Executive, LCT. “We remain on track to meet our goal of completing clinical trials of DIABECCELL by 2015 and having a product commercially available by 2016.”

DIABECCELL is a breakthrough treatment for people with unstable type 1 diabetes and is the first islet transplant treatment that does not require ongoing administration of debilitating immunosuppression drugs. DIABECCELL is owned by the joint venture company Diatranz Otsuka Limited, in which LCT and Otsuka Pharmaceutical Factory both have a 50% interest.

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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<sup>®</sup> 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<sup>™</sup> 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.

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For a summary of DIABECCELL's clinical trial programme please see the DIABECCELL clinical trial update on LCT's website ([www.lctglobal.com](http://www.lctglobal.com) or direct link <http://tinyurl.com/b3lgucw>)

## **About Living Cell Technologies**

Living Cell Technologies (LCT) leads the world in developing cell-based therapeutics to treat diseases with high unmet clinical need. Its proprietary cell encapsulation technology IMMUPEL<sup>™</sup> allows for cell transplantation without the need for immunosuppressant drugs.

LCT's lead therapeutic candidate DIABECCELL<sup>®</sup> is indicated for the treatment of patients with type 1 diabetes, especially those suffering from life threatening episodes of unaware hypoglycaemia (low blood sugar), a dangerous and potentially fatal diabetes complication. DIABECCELL is currently in Phase II clinical trials in both New Zealand and in Argentina.

In 2011, LCT formed a partnership with Otsuka Pharmaceutical Factory Inc (OPF) in which the joint venture Diatranz Otsuka Limited (NZ) was established. Valued at A\$50m on formation, LCT vested the DIABECCELL product and associated IP into the JV, while OPF vested A\$25m to fund the final phase of development of DIABECCELL through to market approval. Both LCT and OPF are 50:50 shareholders in the current and future value generated by DIABECCELL and the associated IP.

LCT has also developed NTCELL<sup>®</sup>, a choroid plexus cell product, to treat neurodegenerative diseases such as Parkinson's disease and stroke. NTCELL's trial results indicate potential for protecting, repairing and possibly regenerating brain tissue which would otherwise die.

LCT is incorporated in Australia. Research and development, operations and manufacturing facilities are based in New Zealand.

## **LCT Disclaimer**

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