

Living Cell Technologies Limited

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ASX: LCT **OTCQX:** LVCLY

ASX ANNOUNCEMENT

'First-in-man' implant of regenerative cell therapy in Parkinson's disease

20th September 2013: Sydney, Australia & Auckland, New Zealand – Living Cell Technologies Limited (LCT) today announced that the first patient has been successfully implanted in the Phase I clinical trial of the regenerative cell therapy NTCELL® – a potential treatment for Parkinson's disease.

The pioneering brain surgery was conducted at Auckland City Hospital and the patient has recovered well so far. An MRI scan taken the day after the surgery indicated that the NTCELL capsules have been implanted at their intended target. The patient and family have requested privacy and no contact with the media.

The Phase I clinical trial is an open label investigation of the safety and clinical effect of NTCELL in four people who have been diagnosed with Parkinson's disease for at least four years. The first patient will now be monitored for two months to confirm no serious adverse safety events. At that time, the independent data safety monitoring board (DSMB) will consider the safety data and advise if the implants for the remaining three patients can proceed.

The trial Principal Investigator is Dr Barry Snow (MBChB, FRACP, FRCPC), an internationally recognised clinician and researcher in Parkinson's disease who leads the Auckland Movement Disorders Clinic at the Auckland District Health Board. "The team are pleased with how well the patient tolerated the procedure itself," says Dr Snow. "The surgery is relatively straightforward in neurosurgery terms, and we have taken full advantage of well-established techniques, which lowers the clinical risk. The patient will now be monitored closely by the team over the next two months."

Dr Andrea Grant, CEO and Managing Director of LCT says: "This is a significant milestone and a world first. It has taken a great deal of hard work, clinical and scientific endeavour to get to this and so of course we are excited. The purpose of this "first-in-man" study is to demonstrate the treatment is safe. Provided this trial is successful, future trials will further assess the extent of clinical benefit that patients might gain."

In the clinical trial, NTCELL is injected under guidance by neuroimaging into the affected area of the human brain where substantial death of neurons and other cells has occurred. The cell therapy is comprised of choroid plexus cells, which are naturally occurring 'support' cells for the brain. LCT's propriety technology IMMUPEL® coats the implanted cells to protect them from attack by the patient's immune system.

The scientific basis for the Phase I clinical trial in humans was established from the published preclinical trial of NTCELL[®] in a non-human primate model of Parkinson's disease. The preclinical results indicate that NTCELL can protect and regenerate brain tissue that would otherwise be lost, potentially delaying or even preventing the effects of Parkinson's disease.

"Unlike current therapy options for Parkinson's disease, NTCELL may be neuroprotective and offers people living with the disease the hope of being able to halt disease progression and restore quality of life," says Dr Grant.

LCT and Otsuka Pharmaceutical Factory (OPF) are co-developing NTCELL as a treatment for Parkinson's disease. Under the agreement, LCT has already received an A\$3m cash payment and OPF



is funding all of the research and development costs associated with the Phase I clinical trial, estimated at AU\$2.1m. In addition, LCT will receive a second cash payment of AU\$2m provided the DSMB authorise the remaining three implants later in the year.

- Ends -

For further information: www.lctglobal.com

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About Parkinson's disease

- Parkinson's disease affects approximately 4 million people worldwide.
- It is a progressive neurological condition which is characterised by a loss of brain cells that produce dopamine a neurotransmitter that conveys messages between brain cells to ensure effective movement and planning of movement as well as many other types of neurons.
- Most pharmaceutical treatment options focus on restoring the balance of dopamine and other neurotransmitters.
- For many patients, drugs become ineffective as the severity of symptoms increases over time
- When dopamine treatments are no longer useful, some patients are treated with Deep Brain Stimulation (DBS) a medical device is surgically implanted in the brain in order to send electrical impulses to regions of the brain involved in the control of movement.
- DBS does not impact on disease progression, is not curative or neuroprotective and does not improve major non-motor symptoms such as cognition, poor balance or autonomic dysfunction.



NTCELL preclinical data

- The preclinical trial of NTCELL in a non-human primate model of Parkinson's disease was published in the Journal of Parkinson's Disease – available via Open Access at: http://iospress.metapress.com/content/e0003031197w8148/fulltext.pdf.
- NTCELL demonstrated significant:
 - Recovery from movement abnormalities.
 - Improvements in neurological defects.
 - Increase in neural connections and number of dopamine-producing neurons in the affected area of the brain.
- Improvements were seen within two weeks and lasted for at least six months, the trial endpoint.
- NTCELL implants were well tolerated with no evidence of inflammation or other adverse reaction.

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: DIABECELL® 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 with international pharmaceutical company Otsuka Pharmaceutical Factory (OPF), LCT has secured funding, based on the achievement of clinical milestones, for the clinical development of DIABECELL and the Phase I clinical trials of NTCELL in Parkinson's disease. LCT retains a 50% share of future profits from DIABECELL 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 $^{\text{TM}}$, 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 or follow @lctglobal on Twitter

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.