



## Living Cell Technologies Limited

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

### ASX ANNOUNCEMENT

## LCT receives ethics approval for Phase IIb Parkinson's trial

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**3 February 2016 – Sydney, Australia & Auckland, New Zealand** – Living Cell Technologies has received approval from the Northern A Health and Disability Ethics Committee for the Phase IIb clinical trial of NTCELL<sup>®</sup> for Parkinson's disease. The New Zealand Minister of Health authorised the application to conduct the trial on 12 November 2015.

The Phase IIb trial follows the successful Phase I/IIa trial, which showed excellent safety data and clinically and statistically significant efficacy data in patients with Parkinson's disease one year after NTCELL treatment.

The Phase IIb trial aims to confirm the most effective dose of NTCELL, define any placebo component of the response and further identify the initial target Parkinson's disease patient sub group. The company plans to initiate the trial on 24 February 2016.

If the trial is successful the company will apply for provisional consent and launch NTCELL as the first disease modifying treatment for Parkinson's disease in 2017.

– Ends –

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

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### About NTCELL

NTCELL, a unique cell therapy, is an alginate coated capsule containing clusters of neonatal porcine choroid plexus cells that are sourced from a unique herd of designated pathogen-free pigs bred from stock originally discovered in the remote sub-Antarctic Auckland Islands. Choroid plexus cells are naturally occurring "support" cells for the brain and secrete CSF, which contains a range of factors that support nerve cell functions and protective enzymes that are crucial for nerve growth and healthy functioning. In NTCELL, the porcine choroid plexus cells are coated with LCT's proprietary technology IMMUPEL<sup>™</sup> to protect them from attack by the immune system. Therefore, no immunosuppressive regimen is required for treatment.

Following implantation into a damaged site within the brain, NTCELL functions as a neurochemical factory producing CSF and secreting multiple nerve growth factors that promote new central nervous system (CNS) growth and repair disease-induced nerve degeneration while potentially removing waste products such as amyloids and proteins.

NTCELL has the potential to treat neurodegenerative diseases because choroid plexus cells help produce CSF as well as a range of neurotrophins (nerve growth factors) that have been shown to protect against neuron (nerve) cell death in animal models of disease. NTCELL has been shown in preclinical studies to regenerate damaged tissue and restore function in animal models of Parkinson's disease, stroke, Huntington's disease, hearing loss and other non-neurological conditions, such as wound healing. In addition to Parkinson's disease, NTCELL has the potential to be used in a number of other CNS indications, including Huntington's, Alzheimer's and motor neurone diseases including amyotrophic lateral sclerosis (ALS).

### **About Parkinson's disease**

Parkinson's disease is a progressive neurological condition 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) and many other types of neurons. People with Parkinson's disease experience reduced and slow movement (hypokinesia and bradykinesia), rigidity and tremors.

Parkinson's disease is the second most common neurodegenerative disorder after Alzheimer's disease, affecting approximately 4 million people worldwide. The average age of onset is 60 years, and the incidence increases with age. Men are one and a half times more likely to have Parkinson's disease than women.

Current treatments for Parkinson's disease are symptomatic and do not reverse or slow the degeneration of neurons in the brain. Most existing pharmaceutical treatment options focus on restoring the balance of dopamine and other neurotransmitters. The effectiveness of dopamine replacement therapy declines as the disease progresses. When dopamine treatments are no longer useful, some patients are treated with Deep Brain Stimulation (DBS), in which 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. While DBS leads to short-term symptomatic improvement, it does not impact disease progression and is not curative or neuroprotective.

### **About Living Cell Technologies**

Living Cell Technologies Limited (LCT) is an Australasian biotechnology company improving the wellbeing of people with serious diseases worldwide by discovering, developing and commercialising regenerative treatments which restore function using naturally occurring cells.

LCT's lead product, NTCELL<sup>®</sup>, is an alginate coated capsule containing clusters of neonatal porcine choroid plexus cells. After transplantation NTCELL functions as a biological factory, producing factors to promote new central nervous system growth and repair disease-induced nerve degeneration.

The Phase I/IIa NTCELL clinical trial in New Zealand for the treatment of Parkinson's disease met the primary endpoint of safety and showed encouraging clinical efficacy improvements. Results from this trial have been used to design a larger Phase IIb trial to evaluate its potential as a disease-modifying treatment for patients with Parkinson's disease. It has the potential to be used in a number of other central nervous system indications such as Huntington's, Alzheimer's and motor neurone diseases.

LCT's proprietary encapsulation technology, IMMUPEL<sup>™</sup>, allows cell therapies to be used without the need for co-treatment with drugs that suppress the immune system.

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

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

**Forward-looking statements**

This document may contain 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 commercialisation 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 materialise, 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.