

## Living Cell Technologies Limited

ACN: 104 028 042 ASX: LCT OTCQX: LVCLY

### **ASX ANNOUNCEMENT**

# Group 2 Parkinson's trial patients' treatment completed

**22 December 2016 – Sydney, Australia & Auckland, New Zealand –** Living Cell Technologies Limited has completed treatment of all six patients in group 2 of the Phase IIb clinical trial of NTCELL<sup>®</sup> for Parkinson's disease, at Auckland City Hospital. Four patients had 80 NTCELL microcapsules implanted into the putamen on each side of their brain, and two patients had sham surgery with no NTCELL implanted. To date there are no safety issues in any of the six patients.

The first five patients in the group were treated between 12 and 19 November. The ability to treat five patients in eight days demonstrates that the company's internal procedures are working well and the team is meeting the very high standards demanded by the clinical trial protocol.

Auckland City Hospital's purchase of an additional stereotaxic frame means that the neurosurgical team is able to increase the number of procedures performed. This has contributed to the increased treatment rate in this second group of patients, as has the scheduling of dedicated surgical sessions for trial patients.

Dr Barry Snow's recent presentations to Parkinson's New Zealand in Auckland were instrumental in identifying patients who met the treatment criteria for the study, some of whom were treated in group 2.

The next step is for the Data Safety Monitoring Board to consider giving approval to treat the six patients in group 3 with the next dose of NTCELL (120 microcapsules implanted into the putamen on each side of their brain).

The company plans to complete group 3 by the end of February 2017. The company is blind to the results until 26 weeks after completion of group 3 of the trial, at which point the patients who received the placebo will receive the optimal dose of NTCELL.

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. If the trial is successful, the company will apply for provisional consent to treat paying patients in New Zealand in Q4 2017.

"Our goal, subject to continued satisfactory data, is to obtain provisional consent and launch NTCELL as the first disease modifying treatment for Parkinson's disease early in 2018," says Dr Ken Taylor, CEO of LCT.

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For further information: <u>www.lctglobal.com</u>

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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 cerebrospinal fluid (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 propriety 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.

LCT has global patents pending entitled "Treatment of CNS disease with encapsulated inducible choroid plexus cells". LCT also has gene chip analysis of NTCELL identifying multiple growth and trophic factors, antioxidants, chaperone molecules and other bioactive components.

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 7 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 reversed progression of the disease two years after implant. Results from this trial were used to design a larger Phase IIb trial 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. This trial commenced in March 2016. If the trial is successful, the company will apply in late 2017 for provisional consent to treat paying patients in New Zealand and launch NTCELL as the first disease modifying treatment for Parkinson's disease.

In addition to Parkinson's disease, NTCELL has the potential to be used in a number of other central nervous system indications, including Huntington's, Alzheimer's and motor neurone diseases including amyotrophic lateral sclerosis (ALS).

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 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.