

## **Living Cell Technologies Limited**

**ACN:** 104 028 042

ASX: LCT OTCQX: LVCLY

## **ASX ANNOUNCEMENT**

# NTCELL® Phase I/IIa Parkinson's trial update

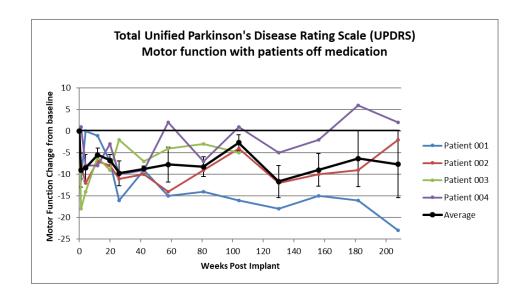
Patient data 4 years after implantation show safety and some efficacy

**21 January 2019 – Sydney, Australia & Auckland, New Zealand –** LCT has the data from the 4 year follow up of the three remaining patients in the Phase I/IIa study of NTCELL<sup>®</sup> for Parkinson's disease.

This is the continuation of our first clinical study of NTCELL to confirm safety of NTCELL. In all patients the primary endpoint of this study of safety was met.

Four patients with advanced Parkinson's disease who were not responding to symptomatic treatment and were listed for DBS treatment, received implants of 40 NTCELL capsules unilaterally in the putamen.

Patient 1, four years after implantation continues to show a clinically significant improvement in Parkinson's disease symptoms as measured by UPDRS and the motor subscale. Patient 3, after two years of follow-up requested DBS treatment and withdrew from further evaluation. Patients 2 and 4, four years after implantation show no change from their study entry score.



LCT CEO, Dr Ken Taylor says, "This data should be regarded as individual case studies. The small patient number and variability of the disease limit conclusions regarding efficacy. It is encouraging that no safety issues have occurred."

Efficacy is measured using the Unified Parkinson's Disease Rating Scale (UPDRS) which consists of four sub-scales, one of which is Motor Examination. All measurements reported above are when patients are off symptomatic treatments. The UPDRS score increases by approximately 4 to 5 points each year as Parkinson's disease progresses.

Efficacy data from the Phase IIb NTCELL clinical study 2 years after implantation should be complete in all the treatment groups and available in May 2019.

#### - Ends -

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#### **About NTCELL®**

NTCELL 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™ 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 filed PCT application No. PCT/US2016/032543 entitled "Treatment of CNS disease with encapsulated inducible choroid plexus cells" and US application No. 15/154,709 was published 15 December 2016. LCT also has gene chip analysis of NTCELL identifying multiple growth and trophic factors, antioxidants, chaperone molecules and other bioactive components.

### **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®, is an alginate coated capsule containing clusters of neonatal porcine choroid plexus cells. After implantation 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 clinical trial of NTCELL for the treatment of Parkinson's disease, in New Zealand, met the primary endpoint of safety and halted the progression of the disease three 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.

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 $^{\text{\tiny{TM}}}$ , allows cell therapies to be used without the need for co-treatment with drugs that suppress the immune system.

LCT is also advancing research collaborations with the University of Auckland to identify products that are candidates for out licensing to global pharmaceutical companies.

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," "probable", "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.