



## Living Cell Technologies Limited

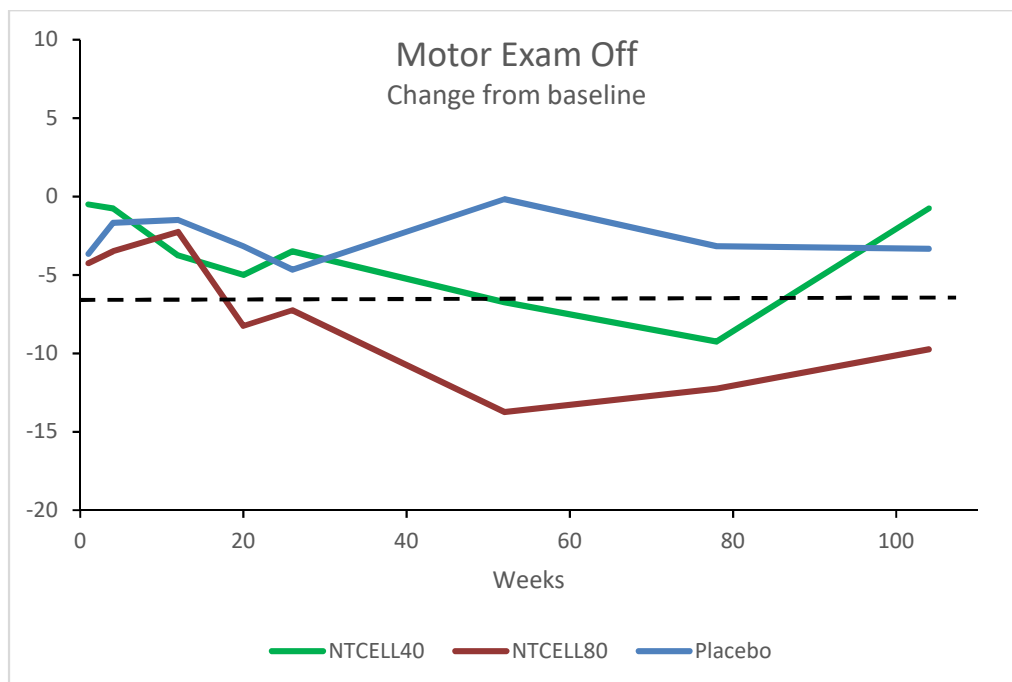
**ACN:** 104 028 042  
**ASX:** LCT  
**OTCQX:** LVCLY

### ASX ANNOUNCEMENT

## NTCELL<sup>®</sup> Parkinson's trial – 2 year data analysis shows successful outcome

**23 July 2019 – Sydney, Australia & Auckland, New Zealand** – The entire data for the two years of the Phase IIb trial of NTCELL<sup>®</sup> in Parkinson's disease, examining the effectiveness of encapsulated pig choroid plexus as a treatment of moderate to late stage Parkinson's disease, has now been extensively analysed by statisticians and other experts.

The key parameter used for assessment was motor function in the off state, that is, when recipients were not taking anti-Parkinsonian medications, with the scoring being the semi-quantitative UPDRS standard.



There was a clinically relevant effect observed<sup>1</sup> (<-6.45 points from baseline) in both the 80 and 40 capsule group. No clinically relevant effect was seen in the 120 group, with evidence that the transplant site could not accommodate this number of capsules. The effect of 80 capsules was greater than that of 40 capsules.

When the placebo group was included in the analysis, the treatment effect was clinically relevant at weeks 52-104 for the 80 capsule group, and at week 52 for the 40 capsule group. There were no adverse effects.

Thus two years after NTCELL implantation, the criteria of a successful Phase IIb trial were met: safety and dose responsive efficacy compared to a placebo group.

Although successful, the small numbers in the trial necessitate a confirmative larger Phase III study. LCT, with specialist input from its expert Medical Advisory Board, is exploring the feasibility of a further study as it would require additional resources and clinical study design.

"The outcome is gratifying but larger patient numbers are needed to convince regulatory authorities prior to marketing," said Interim Chairman Professor Bernie Tuch, "The Board is now examining its options for the future use of NTCELL as a treatment for Parkinson's disease."

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

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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 proprietary 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.

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

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

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<sup>1</sup> Hauser RA et al. Minimal clinically important difference in Parkinson's disease as assessed in pivotal trials of pramipexole extended release. *Parkinson's Dis* 2014; 2014: 4671312014. doi: 10.1155/2014/467131.

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.

As well as NTCELL, LCT is also advancing research collaborations with the University of Auckland to identify products that are candidates for out licensing to global pharmaceutical companies. Projects that have been initiated target obesity and migraine where the lead product candidates utilise patented novel peptide synthetic chemistry technology. LCT will provide updates on these projects later this quarter.

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," "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.