



Living Cell Technologies Limited

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ASX ANNOUNCEMENT

NTCELL clinical trial: Recruitment of further patients approved

25 November 2013 – Sydney, Australia & Auckland, New Zealand – Living Cell Technologies Limited today announced that the independent data safety monitoring board (DSMB) has reviewed the safety data from the initial patient in the Phase I/IIa clinical trial of NTCELL and advised that implants for the additional three patients in the trial can proceed.

The Phase I/IIa clinical trial is an open label investigation of the safety and clinical effects of NTCELL in four patients who have been diagnosed with Parkinson's disease for at least five years. The trial is being run at Auckland City Hospital under the guidance of Principal Investigator Dr Barry Snow.

Dr Andrea Grant, Managing Director of LCT, says "We are very pleased that the DSMB has given approval for us to proceed with implants for the remaining three patients in this Phase I/IIa trial. The initial safety data from the clinical trial is consistent with that documented in the preclinical trial with non-human primates which was recently published in the Journal of Parkinson's Disease. We understand from the clinical team that the patient is well, all things considered."

The DSMB is comprised of three experts in the field and provides independent, expert advice to LCT on the continuing safety of the trial participants, as well as on the continuing validity and scientific merit of the trial. In making the decision to approve implants for the additional three patients the DSMB primarily considered safety data obtained from the first patient implanted with NTCELL in September of this year. This data included clinical and biochemical assessments at both one week and one month post-implant as well as magnetic resonance imaging (MRI) of the patient's brain at both one day and two months post-implant.

"The primary purpose of this Phase I/IIa study is to demonstrate the safety of NTCELL as a potential cell-therapy in the treatment of Parkinson's disease," says Dr Grant. "The first opportunity we will have to obtain an indicative assessment efficacy will be when all four patients complete six months of follow-up post their first implant. Whilst this is some way off, we have met another significant milestone in being able to secure DSMB approval to go on and implant all four patients."

LCT and Otsuka Pharmaceutical Factory (OPF) are co-developing NTCELL as a treatment for Parkinson's disease. Under the terms of the agreement, LCT expects to receive a second cash payment of A\$2m from OPF as a result of the DSMB authorising the recruitment of the remaining three patients. LCT has already received an A\$3m cash payment from OPF in return for the option to license NTCELL. In addition, OPF is funding all of the research and development costs associated with the Phase I/IIa clinical trial, estimated at A\$2.1m. Thus, this partnership provides both

immediate income to LCT as well as funding for the ongoing clinical development of NTCELL in Parkinson's, the latter provided the Phase I trial meets its endpoints.

– 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: DIABECCELL, for the treatment of Type 1 diabetes and NTCELL, which is in Phase I/IIa clinical trials in New Zealand for the treatment of Parkinson's disease.

Through an innovative joint venture, Diatrans Otsuka Limited (DOL) with international pharmaceutical company Otsuka Pharmaceutical Factory (OPF), LCT has secured funding, based on the achievement of clinical milestones, for the clinical development of DIABECCELL and the Phase I/IIa clinical trials of NTCELL in Parkinson's disease. LCT retains a 50% share of future profits from DIABECCELL 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™, 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.