



Living Cell Technologies Limited

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ASX ANNOUNCEMENT

Statement on NTCELL Phase I clinical trial

20 February 2014 – Sydney, Australia & Auckland, New Zealand – Living Cell Technologies Limited provides the following statement of facts regarding the withdrawal from publication of a pre-clinical study of NTCELL and the impact of this on the clinical trial currently underway at Auckland City Hospital. This is in response to a story from the ABC about the trial and concerns that inaccurate statements in the widely disseminated ABC report could create a false market.

Summary of facts

- On 19th December, 2013, LCT announced it was withdrawing the publication of a pre-clinical study of the beneficial effects of NTCELL in a rat model of Parkinson's disease¹, and that this data would also be removed from all regulatory dossiers.
- None of the pre-clinical studies supporting the potential safety of NTCELL in humans have been withdrawn
- The Phase I/IIa clinical trial of NTCELL for Parkinson's disease has not been stopped.
- There is currently one patient in the trial who is continuing with all assessments. The clinical team reports that the patient is in good health. The patient continues to explicitly request privacy, which the company respects.
- The NZ regulatory authority, Medsafe, authorised the trial following a substantive and proper review of the clinical trial application submitted by LCT. This application contained evidence gathered from multiple pre-clinical studies of the potential safety and efficacy of NTCELL. Only one of these pieces of evidence is affected by the withdrawal of the publication.
- The most compelling evidence of the potential of NTCELL as a treatment for Parkinson's disease arises from the study of the effects of NTCELL in a non-human primate (monkey) model of Parkinson's disease. This study was published in the Journal of Parkinson's disease last year². This publication has not been withdrawn and the data remains in the regulatory submission.
- The patient who received NTCELL over six months ago has not experienced any serious adverse events that give rise to concern over the safety of NTCELL.

¹ SJM Skinner, H Lin, MS Geaney, T Gorba, RB Elliott, PL J Tan, titled "Restoration of motor control and dopaminergic activity in rats with unilateral 6-hydroxy-dopamine lesions" Regen. Med 2011; 6: 319-326.

² Luo X-M, H Lin, W Wang, MS Geaney, L Law, S Wynyard, SB Shaik, H Waldvogel, RLM Faull, RB Elliott, SJM Skinner, JE Lee and P L J Tan. Recovery of neurological functions in non-human primate (NHP) model of Parkinson's disease by transplantation of encapsulated neonatal porcine choroid plexus cells. Journal of Parkinson's Disease 2013; 3: 275-29.

- Recruitment of further patients to the trial has been paused voluntarily by the company. This is to allow the data safety monitoring board (DSMB) sufficient time to reach its own determination on whether the withdrawal of the single rat efficacy study from the pre-clinical evidence base creates a significant safety risk to any subsequent patients who may be recruited. .

Living Cell Technologies managing director, Dr Andrea Grant, said "We take our responsibility to patients, clinicians and regulators very seriously. So, as a precaution we have simply paused recruitment to give the DSMB the opportunity to independently form their own view. Supporting the DSMB in its deliberations is our focus right now, and once we have their view, we will make further announcements."

– Ends –

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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, Diatranz 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 (OTCOX: 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

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