



Living Cell Technologies Limited

CAN: 104 028 042
ASX: LCT
OTCQX: LVCLY

ASX ANNOUNCEMENT

Withdrawal of NTCELL pre-clinical study

19 December 2013 – Sydney, Australia & Auckland, New Zealand – Living Cell Technologies Limited today announced that it is withdrawing the publication of the pre-clinical study of the effects of NTCELL in a rat model of Parkinson’s disease. The data will also be withdrawn from all regulatory documentation.

The study in question was conducted by LCT between 2007 and 2009, and the results published in *The Journal of Regenerative Medicine* in 2011¹.

The publication is being withdrawn following an internal quality assurance (QA) audit which showed that the source data for the study held on file at LCT are incomplete and therefore the efficacy conclusions in the publication cannot be confirmed.

The withdrawal of the rat efficacy data does not in itself present a safety risk with regard to the use of NTCELL in humans. Nonetheless, as a precautionary measure LCT has placed a hold on any further patient recruitment into the human Phase I/IIa clinical study that is currently underway at Auckland City Hospital. This is to allow the company to work with the New Zealand medicines regulator (Medsafe) and the data safety monitoring board (DSMB) to fully understand the impact of the withdrawal of the rat efficacy data on the Phase I clinical trial.

Dr Andrea Grant, Managing Director of Living Cell Technologies said, “Regular quality audits of source data are a founding principle of LCT’s commitment to the safety of patients in our clinical trials. It is most unusual for these audits to result in the withdrawal of data from a clinical trial application, but our priority as a commercial company is always on patient safety and therefore full disclosure. Whilst it is reassuring to know the withdrawal of the efficacy data does not pose safety risks, it is the right and proper thing to do to place the trial on hold whilst we thoroughly investigate the findings of the audit.”

The first person implanted with NTCELL in the Phase I/IIa study continues to do well since their implant in September 2013. They will continue to be managed by the clinical team according to the clinical trial protocol. The patient’s explicit request for privacy remains in place.

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" was published in Regen. Med 2011; 6: 319-326.*

LCT and Otsuka Pharmaceutical Factory (OPF) are co-developing NTCELL as a treatment for Parkinson's disease. A second cash payment of A\$2m which was due from OPF to LCT as a result of the DSMB authorising the recruitment of the remaining three patients to the study is now not expected to be received until patient recruitment into the trial is recommenced.

– Ends –

For further information: www.lctglobal.com

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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: DIABECELL, 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 DIABECELL and the Phase I/IIa clinical trials of NTCELL in Parkinson's disease. LCT retains a 50% share of future profits from DIABECELL 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

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