

# Living Cell Technologies Limited Company Announcement

# Authorisation of Phase I trial of NTCELL® in Parkinson's disease

**4 October 2012: Sydney, Australia & Auckland, New Zealand –** Living Cell Technologies Limited (ASX: LCT; OTCQX: LVCLY) has received authorisation from the New Zealand Minister of Health to proceed with Phase I clinical trials of NTCELL for Parkinson's disease.

The approval means LCT is on track to commence the first in-human trials in Q1 2013.

The clinical trial will be a Phase I open label investigation of the safety and clinical effect of NTCELL in people with Parkinson's. The study will last up to 60 weeks and involve patients that have been diagnosed with Parkinson's for at least four years.

The treatment being trialled involves transplanting choroid plexus cells from the Auckland Island pig herd into the brain. Choroid plexus cells are naturally occurring "support" cells for the brain and when transplanted can help protect the brain and repair damaged nerve tissue. These cells will be encapsulated with LCT's IMMUPEL™, to prevent the immune system from rejecting them as foreign.

Trial patients will receive either NTCELL treatment or the current gold standard of treatment for their symptoms, deep brain stimulation.

The Principal Investigator for the trials will be Dr Barry Snow (MBChB, FRACP, FRCPC), an internationally recognised clinician and researcher in Parkinson's disease who leads the Auckland Movement Disorders Clinic at the Auckland District Health Board.

"Parkinson's is a disorder which clinicians can help manage but can't reverse, so this represents an exciting new potential option for patients," said Dr Snow. "These clinical trials will also help raise public awareness of the disorder, which in turn helps improve the way the disorder is looked after generally."

"Receiving regulatory approval to conduct clinical trials is a critical step in developing a treatment for this debilitating condition," said Dr Andrea Grant, Chief Executive of LCT. "The unprecedented results of our preclinical studies suggest that NTCELL can protect brain tissue which would otherwise die, potentially delaying or even preventing the effects of Parkinson's."

The results of pre-clinical studies showed an increase in dopamine producing neurons, improvements in movement and neurological defects, together with good tolerance with no evidence of inflammation or other adverse reaction. The improvements were seen within two weeks and lasted for at least six months, the trial endpoint.

#### About Parkinson's disease

Parkinson's disease is the second most common neurodegenerative disorder after Alzheimer's disease and affects four to six million people worldwide. In Parkinson's, reduced dopamine levels in the brain lead to movement-related symptoms such as tremor, rigidity and slowness of movement. Cognitive and behavioural symptoms are often observed later. The effectiveness of current treatments, which focus on dopamine replacement, decline as the disease progresses. Moreover, current treatments are symptomatic and do not reverse or slow the degeneration of the brain.

**Ends** 

For further information: www.lctglobal.com

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## **About Living Cell Technologies**

Living Cell Technologies (LCT) leads the world in developing cell-based therapeutics to treat diseases with high unmet clinical need. Its proprietary cell encapsulation technology IMMUPEL™ allows for cell transplantation without the need for immunosuppressant drugs. LCT's lead therapeutic candidate DIABECELL® is indicated for the treatment of patients with type 1 diabetes, especially those suffering from life threatening episodes of unaware hypoglycaemia (low blood sugar), a dangerous and potentially fatal diabetes complication. DIABECELL is currently in Phase II clinical trials in both New Zealand and Argentina. In 2011, LCT formed a partnership with Otsuka Pharmaceutical Factory Inc (OPF) in which the joint venture Diatranz Otsuka Limited (NZ) was established. Valued at A\$50m on formation, LCT vested the DIABECELL product and associated IP into the JV, while OPF vested A\$25m to fund the final phase of development of DIABECELL through to market approval. Both LCT and OPF are 50:50 shareholders in the current and future value generated by DIABECELL and the associated IP.

LCT has also developed NTCELL®, a choroid plexus cell product, to treat neurodegenerative diseases such as Parkinson's disease and stroke. NTCELL's trial results indicate potential for protecting, repairing and possibly regenerating brain tissue which would otherwise die. LCT is incorporated in Australia. Research and development, operations and manufacturing facilities are based in New Zealand.

#### **LCT Disclaimer**

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