



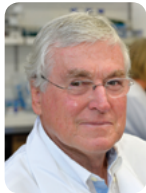
LCT living insights

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Published on an occasional basis, *Living Insights* is a source of up-to-date information for followers of the Australasian biotechnology company Living Cell Technologies (LCT)

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Message from the CEO

Welcome to this issue of *Living Insights*.

Living Cell Technologies is in a good position, with international exposure and recognition, as we work towards our goal of developing and commercialising the first disease-modifying treatment for Parkinson's. We're encouraged by the positive activity on the share market and welcome our new investors.

If you haven't already, I urge you to watch the video on our website featuring Carol, a patient on the Phase I/IIa trial of NTCELL®. She's courageous, candid and articulate about what it's like to live with Parkinson's and how NTCELL has changed her life.

▶ [Watch the video here](#)

Ken Taylor
CEO

The Phase IIb clinical trial of NTCELL in Parkinson's disease is underway

Since the trial is placebo-controlled LCT is blinded to which patients have received NTCELL and which have received the placebo.

While ASX regulations constrain what we can disclose about individual patients in the trial we can report that manufacture and implantation have begun. The intention is to complete implants in the first group of six patients by the end of August. Then the Data Safety Monitoring Board (DSMB) has to approve the process before implants can begin for the second group. The aim is to have all patients in group two completed by the end of 2016 and group three completed by February 2017.

Results for the first three groups should be available early in the second half of next year at which point the study will be unblinded, and the patients who received the placebo will receive an implant of NTCELL at the dose determined to be most effective.

Over the past two years LCT has achieved all milestones so we're confident the study will be completed and results known in 2017.

International Congress of Parkinson's Disease and Movement Disorders

The plenary session at the Congress in Berlin was most informative. The overwhelming consensus seems to be that Parkinson's disease is not one disease but a number of heterogeneous diseases, characterised by movement disorders and age-related degeneration of the putamen, an area of the striatum located in the midbrain. In our clinical studies NTCELL is implanted into the putamen.

Variations in the disease require flexible treatment which NTCELL provides. The NTCELL alginate capsule allows penetration of incoming hormonal signals that will trigger the selective and timely release of nerve growth factors that are appropriate for each individual patient. Classifying the movement disorder disease (or diseases) is only useful if it helps with treating the disease.

The plenary session also emphasised the importance of long-term patient follow-up data to reach conclusions regarding efficacy in clinical trials.

Poster presentation

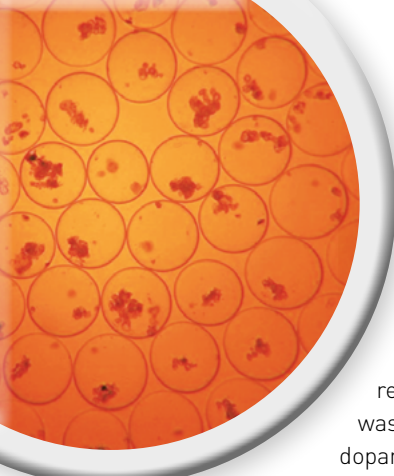
At the Congress, Dr Barry Snow presented 81 week+ data on the safety and clinical effects of NTCELL in patients with Parkinson's disease.

▶ [You can view the poster here](#)

The presentation was very well received. Impressions are that LCT is at the cutting edge of Parkinson's research and that NTCELL is a novel technology. The long-term data from the Phase I/IIa trial, demonstrating that all measurements of Parkinson's disease showed improvement, is impressive. Those at the Congress also felt that it is unlikely that the efficacy of NTCELL can be placebo at 81 weeks post implant.

There was also general agreement that the design of the Phase IIb trial is very well thought out and will produce answers to the key questions that will enable NTCELL to proceed to a product launch.





Cell therapies are the future

New therapies in development for Parkinson's disease can be grouped in three areas of research: pharmaceuticals, stem cells and cell therapies.

Pharmaceuticals have focused on dopamine replacement therapy. The gold standard, Levodopa, was launched 50 years. Unfortunately, no new dopaminergic agent has effectively improved on this since then. Moreover, all dopaminergic agents including Levodopa treat symptoms only and are effective for a limited time.

They do not stop the progression of Parkinson's disease.

Meanwhile companies researching stem cell treatments are foundering. Stem cells are difficult and costly to produce and are very unstable. Once they're reprogrammed they have a short shelf life, usually hours. There have been numerous stories in the media questioning whether stem cell treatments are all hype or the next big hope for the future of regenerative medicine.

In May this year Reuters reported that StemCells Inc was winding down operations after the company terminated a mid-stage trial testing its therapy in spinal cord injury. The treatment's cost efficacy ratio apparently could not justify continuing the study, given the financial resources the company had available.

► [Read the Reuters article here](#)

In 2011, Geron Corp said it would pull the plug on its stem cell research and focus on its experimental cancer treatments. Consequently, analysts are not optimistic about the future of other stem cell research companies in the field of regenerative medicine.

Neuroprotection or neurorestoration will require multiple and targeted therapies. This can only be achieved with cell therapy. The choroid plexus cells in NTCELL are not stem cells that have been reprogrammed. They are naturally occurring cells and are stable for over 60 days once purified. The choroid plexus is critical to the normal functioning of the brain as it provides neuroprotection and produces cerebrospinal fluid (CSF). Aging causes reduction in function, and the production of CSF halves. NTCELL is restorative: it does this by a pleiotropic effect having the capacity to synthesise and release a host of neuroprotective agents which we have identified by microarray and gene chip analysis.

Precision medicine

Not all treatments work for everybody with Parkinson's disease due to the heterogeneity of the disease. As in many other chronic illnesses current research is focused on developing treatments to provide personalised response to these heterogeneous diseases. Success would promise greater efficacy which would help justify the cost of expensive targeted treatments.

This goal has led to the term 'precision medicine' being the target or requirement for advanced and expensive treatments that promise disease modification.

Due to its ability to respond specifically to signals in individual patients according to their neurodegenerative disease type and deterioration, NTCELL treatment certainly has the qualities required for a precision medicine. This is reflected in efficacy data in the clinical data presented at the Berlin conference.

All patients in the Phase I/IIa trial improved in all measurements of Parkinson's after NTCELL implantation. But there is obvious variation in each patient's individual rate and type of improvement. That would be expected and is encouraging as it is consistent with NTCELL's adaptive ability and plasticity.



BIO International Convention

At the BIO International Convention in June, LCT had a series of meetings with a broad range of attendees, including pharmaceutical and biotech companies, universities and investors, discussing scale up technologies, partnering opportunities and potential investment.

This was an excellent opportunity to gauge our progress and assess the competitive landscape. The general sentiment was very positive.

LCT is making good progress and our science and clinical trial programme are world class.

We had a number of interesting meetings to discuss potential opportunities for the commercialisation of NTCELL once the current Phase IIb trial is completed next year.



Photo by: Clifton Fuller

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