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living insights

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.

This issue outlines the projects currently underway at LCT and other initiatives. I attended a number of overseas conferences during June, and insights and information gathered at these meetings have informed our prioritisation of these projects.

Ken Taylor, CEO

Other pipeline projects

We have initiated projects that have therapeutic targets that include migraine, a particular malignant brain tumour and obesity. The goal is to identify a patented small molecule that can be progressed to proving clinical safety and efficacy.

We expect to have preliminary data on these projects by November and I look forward to updating you on progress at that time.

Funding

We have just received confirmation from Callaghan that our 20 percent research and development rebate, which was expiring this year, has been extended for a further two years. This rebate, together with the considerable savings we have made by downsizing LCT staff to retain only the staff necessary to support our current activities, means that we do not need to raise further capital to reach the important milestones in the above projects. Moreover, we will make further savings by relocating LCT to a more efficient office closer to the University of Auckland Medical School and Auckland City Hospital on 1 October.

Product development updates

NTCELL for Parkinson's disease

As previously announced, we are continuing to monitor the patients in the Phase IIb study of NTCELL for Parkinson's disease.

The next monitoring milestone will be in November, at which time we will have 18-month follow up data on all patients. In May 2019 we expect to have two-year data on these patients.

In October, Principal Investigator Dr Barry Snow will attend the International Congress of Parkinson's Disease and Movement Disorders in Hong Kong. At this meeting, Dr Snow will have confidential discussions with a select number of leading neurologists about the results of the NTCELL trial released to date. The aim of these discussions is to canvass expert opinion on the data we have with a view to determining the next steps for NTCELL.

We regularly receive emails from potential patients and investors enquiring about LCT's next steps with NTCELL as a treatment for Parkinson's disease. While we appreciate the interest, opinions on the data vary widely depending on the position of the emailer – are they a patient, investor or neurologist? The most important opinion for LCT will be that of the regulatory authorities on data relating to quality, safety and efficacy. We will have to satisfy their demands to obtain approval to market NTCELL. Therefore, the focus of LCT's current approach to evaluating the data is dominated by the demands of Medsafe, the New Zealand regulatory authority. We know that our clinical data must demonstrate safety and dose-ranging efficacy, accounting for any placebo effect and being able to describe the sub-population of Parkinson's disease patients that would initially be approved to receive NTCELL treatment. Understandably, the demands of regulatory authorities are necessarily exacting and take no account of emotive or anecdotal narratives.

Timeline: monitoring milestones

November 2018
18-month data on all patients in Phase IIb study

December 2018
Four-year data on remaining patients in Phase I/IIa data

May 2019
Two-year data on all patients in Phase IIb study.

Pericyte Protective Agent

We are making good research progress towards identifying a novel active agent derived from the chemical secretions of NTCELL (encapsulated choroid plexus cells). This research has been of much interest in my discussions with overseas industry contacts. At this stage a Pericyte Protective Agent shows potential to target dementia caused by cerebral vascular abnormalities.

This approach to developing and commercialising a product to treat neurodegenerative disease is attractive. In contrast to cell therapy which requires neurosurgery to deliver active cells, a Pericyte Protective Agent can be synthesised and administered either by injection, or possibly orally.