

Living Cell Technologies Limited

Clinical trials update

Living Cell Technologies (LCT) MD and CEO, Andrea Grant, has just conducted an Open Briefing interview in which she provides updates on the status of DIABECCELL® and NTCELL® clinical trials.

You can read a full transcript [here](#) and listen to audio of part of the briefing [here](#).

Key points covered in the discussion were:

DIABECCELL for type 1 diabetes

- The clinical development for DIABECCELL as a treatment for people with type 1 diabetes is on track and, provided the registration study is successful, it is still the target to launch a commercial product by 2016.
- A 30 patient registration study with a combined endpoint of reduction in unaware hypoglycaemia with no increase in HbA1c is predicted to be sufficient to secure registration in New Zealand by 2016.
- 20 patients for this registration data package will be provided from the study currently ongoing in Argentina (announced as a Phase IIb on 22 November 2012). All 20 patients have been recruited, and eight patients have received their first implants.
- The remaining 10 patients will be recruited in New Zealand once the application for the registration study is accepted by the New Zealand regulator Medsafe, which is expected to occur before year end.
- Once the Medsafe application is approved and the New Zealand patients are recruited, then the 30 patient registration study is established.

NTCELL for Parkinson's disease

- The Phase I clinical trial is underway and we expect the first patient to be consented into the trial in the next fortnight.
- Following consent, the patient will be monitored for eight weeks to establish baseline data, with the implant expected to occur during Q3.
- If the product is shown to be effective in humans, registration in 2018/2019 via a fast-tracked development programme should be achievable. However, the development programme is at an early stage and this target registration date may change, depending on the results of the Phase I and subsequent trials.

FUNDING

- Under the agreement signed with Otsuka Pharmaceutical Factory (OPF) for the co-development of NTCELL for Parkinson's disease, LCT expects to receive the second milestone payment of A\$2 million during late Q3/early Q4 of this year. This payment will occur two months after implant of the first patient, provided that the data safety monitoring board decides it is safe to proceed with the implants for the remaining three patients.
- The Diatranz Otsuka Limited (DOL) 50:50 partnership with OPF continues to provide the funding for the clinical trials of DIABECCELL.

- As of 31 March 2013, LCT has \$4.91m in cash reserves to support approximately \$1.2m per annum of R&D and other activities that are not otherwise funded by the DOL or OPF agreements.