The Living Cell

A quarterly newsletter from Living Cell Technologies

August issue 2009

New Zealand DIABECELL® Trial Starts

Volunteers with type 1 diabetes are being enrolled for the DIABECELL® clinical trial by the team at the Centre for Clinical Research & Effective Practice, Middlemore Hospital in Auckland, New Zealand.

The medical history and blood test results of the volunteer patients have to meet a number of criteria for entering the trial which starts with monitoring of the diabetic status so that baseline records of insulin doses and blood glucose levels are obtained for eight weeks before the pig islet cells are implanted. The monitoring period for the first volunteer should end in late September when the first implant in Auckland is expected.

Dr Koops and Dr Durbin

Dr Kathleen Durbin, Clinical Trial Officer at LCT, is co-ordinating the supply of DIABECELL® from LCT's manufacturing unit to the hospital. Dr Durbin, a graduate from Edinburgh has many years experience managing clinical trials. She has also worked with the international clinical research organisation, Quintiles, in Scotland, UK.

At Middlemore Hospital, the physician assessing the patients is Dr Renate Koops, who worked with diabetes patients in her homeland in The Netherlands. Heading the clinical team is Dr John Baker, Endocrinologist.

Ms Veronica Park, Dr Stuart Ryan, Ms Ruth Withers, Dr John Baker and Ms Patricia Loft at Middlemore Hospital

The New Zealand diabetes trial is another major milestone for LCT. With two diabetes patients from the first study in Russia not requiring insulin following implants with encapsulated pig islet cells, Professor Bob Elliott, LCT Medical Director says he expects to see further benefit in more patients as higher doses of DIABECELL® are used in the New Zealand trial.

LCT's clinical trial in Russia started with a low dose of DIABECELL®. In May 2009, LCT reported preliminary data showing sustained long term clinical benefit in patients treated with the DIABECELL® implant with no remarkable adverse events. Remarkably, two of seven patients given implants are now off insulin injections.

The New Zealand trial extends clinical data to eight more patients, four of whom are to receive double the initial dose used in Russia followed by four patients to receive triple the dose..

DIABECELL® Commercialisation by LCT Biomedical in Russia

Maintaining the momentum we have built in Russia is important and as part of this we have announced the formation of a subsidiary, LCT Biomedical Limited (Russia), to facilitate the commercial development of DIABECELL®.

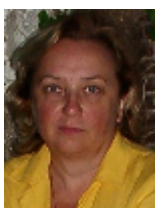
Natalia Dolgova, who is based in Moscow, has been appointed the first director of LCT Biomedical. Mrs Dolgova has 17 years experience in the medical products market in Russia. Her objectives are to obtain regulatory approval for a pivotal clinical study of DIABECELL® in at least two centres in Russia and register the product so that the treatment is available for people with diabetes in Russia. The regulatory process has already been initiated.

Mrs Dolgova will be working closely with Dr Olga Garkavenko, who is LCT's Regional Director for Russia.

We believe this subsidiary is a timely development to advance the positive preliminary results we have seen from the first trial in Moscow. DIABECELL® will be supplied to the Russian market from New Zealand for the foreseeable future.

We believe this Russian commercialisation program is

Dr Olga Garkavenko



Mrs Natalia Dolgova

Message from the CEO

LCT has welcomed a major milestone during this quarter, with the authorisation of the DIABECELL® New Zealand clinical trial. This newsletter highlights LCT's continuing high-priority commitment to the New Zealand and Russian clinical trials and provides detail of LCT's activities in those areas. LCT has also completed a private placement of funds and it is pleasing to see investor support for us to conduct clinical trials that will allow us to get DIABECELL® to people with diabetes and allow us to be commercially successful.

The enrolment of patients for the New Zealand clinical trial has started. There has been widespread international interest in this clinical trial as no other group has come this far with a new treatment designed to normalise the lives of people with insulin dependent diabetes.

Yet another landmark for LCT this quarter has been the creation of a Russian subsidiary – LCT Biomedical Limited – to begin the process of commercialising DIABECELL®. LCT welcomes Natalia Dolgova, the first director of LCT Biomedical Ltd, whose job it will be to make DIABECELL® available for diabetics in Russia.

We also expanded our facilities over the quarter with the opening of our new pathogen-free pig breeding facility in Invercargill, New Zealand. This facility will be used to harvest medical grade tissue from disease-free pig herds.

We are also pleased to report that the Bionic Ear Institute (Melbourne, Australia) has shown that LCT's encapsulated choroid plexus cells (NTCells) can protect nerve cells in the inner ear from degeneration. This is an exciting development for LCT and represents great promise for people with hearing loss, with LCT patenting this research and looking to an opportunity for another product.

This has been a most successful quarter for LCT, and I am pleased to share these developments with you through this newsletter, as we make further strides towards life-changing treatments.

Best wishes,

Dr Paul Tan
Chief Executive Officer

the quickest way to make our innovative treatment available to the wider diabetic community.

Upcoming Events

LCT will be participating in the following conferences:

Clinical Research Conference 2009
Auckland, 20-21 August 2009
"Cell Xenotransplantation – A treatment for Here and Now for Many Diseases?"

Diabetes Youth Conference
Nelson, 21-23 August 2009
"Diabetes Transplant Update"

Queenstown Molecular Biology Conference
Queenstown, 31 August to 5 September 2009
"Cell Based Therapeutics from Animal Models to the Clinic"

IPITA-IXA Joint Congress
Venice, 12-16 October 2009

AusBiotech Conference 2009
Melbourne Convention & Exhibition Centre, Australia
27–30 October 2009

New LCT Pig Breeding Facility

Mr David Collinson, LCT Founding Director, with Mayor of Invercargill Mr Tim Shadbolt

LCT pig breeding facility

LCT's new designated pathogen free pig breeding facility in Invercargill, Southland, New Zealand was formally opened by the Mayor of Invercargill, Mr. Tim Shadbolt at the beginning of July 2009.

The facility is designed to meet health regulations for pig herds used as a source of medical grade tissues. The facility houses separate maternity and holding units and expands LCT's pig facilities to accommodate a sufficient number of pigs to support clinical trials in New Zealand and internationally over the next two years.

LCT's pigs originate from the sub-Antarctic Auckland Islands and are disease free. The new unit ensures that they remain free of viruses, bacteria and parasites.

Latest News

Encapsulated Pig Cells for Hearing Loss

LCT's encapsulated choroid plexus cells (NeurotrophinCell, NTCell) have been shown to protect nerve cells in the inner ear from degeneration in studies done with the Bionic Ear Institute (BEI), Melbourne, Australia.

Professor Rob Shepherd, director of the institute, said, "Results have important implications for strategies to improve the treatment of hearing loss with a combination of a cochlear implant and NTCell".

A cochlear implant is an electronic device often called a 'bionic ear' that is surgically placed into the inner ear (cochlea) of a profoundly deaf person to directly stimulate the remaining auditory nerve.

In the deaf inner ear the auditory nerve cells undergo continuous degeneration. This loss of nerve cells may be prevented by neurotrophins which are growth and support factors for brain and nerve cells.

The BEI research showed that neurotrophin-producing NTCell, together with intracochlear electrical stimulation, protects auditory nerve cells from degeneration in an animal model of hearing loss.

LCT's NTCell implants are porcine choroid plexus cells of the brain that are encapsulated in a gel and when implanted do not require the use of immunosuppressive drugs. NTCell produces many different brain reparative growth and support factors known as neurotrophins. In this study NTCell capsules were successfully implanted into the inner ear of deaf animals.

The scientific results from these studies have been patented. Dr Andrew Wise, BEI scientist, presented the results of the study at the Conference on Implantable Auditory Prosthesis at Lake Tahoe CA, USA in July 2009.

What others say about LCT

LCT media coverage has been overwhelming in this quarter. Here is a sample:

Date	Publication and Article
5 May	Business Spectator – Living Cell's DIABECELL® patients free of insulin injections
23 Jun	BioTechnologyNews.net – NZ finally OKs LCT trials (again)
24 Jun	Australian Life Scientist - Xenotransplantation trial to commence in New Zealand
25 Jun	Prime News - Start of NZ Trials Featured
25 Jun	Herald Sun – New Zealand approves pig cell implants for diabetics
25 Jun	Southland Times – Pig cell trial conditions finalised
3 July	New Zealand Herald Online – Biotech company opens unit to breed pigs for human transplants
6 July	BioSpace Online – LCT commences DIABECELL® commercialisation program in Russia with new subsidiary
8 July	BioSpace Online – LCT encapsulated choroid plexus cells may be used to treat hearing loss
9 July	BioTechnologyNews.net – Early stage LCT research shows promise in deafness
24 July	Business Spectator – Calls to end animal transplant ban
24 July	Dominion Post – Diabetics queue up for pig treatment

Queen Elizabeth II Study Award

Shaun Wynyard, LCT Medical Laboratory Scientist, has won a QE II study award to go to Glasgow Caledonian University where he will be a visiting scientist in the laboratory of Dr Linda Scobie. This laboratory is one of the leading laboratories in the world stduying pig endogenous retroviruses. Shaun says, "I am finalizing the details of my project there and will want to be familiar with the latest laboratory procedures and molecular biology techniques for the retrovirus". Shaun expects to take up the grant and be in Scotland in June –July 2010.

Shaun Wynyard

Dr Olga Garkavenko, LCT Head of Molecular Diagnostics says, "This is a very significant award for Shaun and for LCT, it is important that we remain up to date with the latest scientific knowledge

Xenotransplantation and Regulation in Australia

The announcement that we can proceed with our clinical trials in New Zealand is an exciting development both for LCT as a company and for the wider scientific community. With New Zealand opening the door to xenotransplantation – and the great benefits it potentially offers the medical community – we are hoping that other governments that currently do not allow xenotransplantation trials reconsider their position.

Xenotransplantation in the context of treatment for human disease involves the transplantation of normal living organs, tissues or cells from animals into humans who suffer disease resulting from damage to the corresponding body parts.

The use of animal cells as donors is attractive as human donors are scarce. The two major medical problems of xenotransplantation are the swift rejection of animal derived transplants, and the possibility of harm from infections introduced by such transplants.

This has led to a moratorium on xenotransplantation in countries such as Australia and Canada. In other jurisdictions such as the USA, EU, New Zealand, China and many other countries, guidelines have been compiled to limit precocious research and treatment. The WHO has yet to present a trans-national equivalent.

The principal risk postulated is that of infection with an animal endogenous retrovirus. In the case of primate donors this has occurred and this has been banned. However, the risk of human infection with porcine endogenous retrovirus has been thoroughly researched.

Not all pigs are capable of producing infective virus from the genomic pro virus, or if they do, of producing virus capable of recombination with human viruses. Furthermore, full length retrovirus has been injected intensively on many occasions in the same individuals (haemophiliacs treated with porcine derived clotting factor) without infection. Many hundreds of pig cell transplants into humans or primates have been carried out without causing infection. Indeed, it appears that no animal has ever been productively infected with porcine retroviruses despite thousands of attempts, even including several species of immune suppressed primates with human adapted pig retro viruses.

Where to then with the current moratorium on Xenotransplantation in Australia? Clarification of the potential risks and potential benefits has occurred over the past five years. The major risk bogey – infection with pig endogenous retrovirus - is hypothetical and now perceived as "vanishingly small" and demonstration of benefits have been substantiated. The moratorium on trials of cellular Xenotransplantation is no longer appropriate.

'Duty of Care' is a major responsibility not only of practising health members and researchers, but also health administrators. To unreasonably deny people with diseases such as diabetes and Parkinson's Disease the hope of better treatment gained by xenotransplantation research is unethical. Disease sufferers who volunteer for such limited trials may be the best to decide on whether other issues for consideration – such as cultural and spiritual - affect them.

Prof Bob Elliott
Medical Director

Project Management Institute; 18 June 2009

The Project Management Institute (PMI) invited LCT to provide a speaker for the June meeting of the Auckland branch. Philip Squire, Production Manager, represented LCT giving a 40 minute presentation 'Auckland Islands to Clinic' outlining the DIABECELL® product as a project. This included product development, regulatory issues, supply of trained scientists and materials. There was a lively discussion after the presentation and questions were answered by both Philip, and Marilyn Geaney, Neuroscience Coordinator.

The PMI is a non-profit professional organisation with the purpose of advancing the state-of-the-art of project management. It is a professional association for the project management profession.

and techniques for ensuring that our pigs are free of infections".

Prof Bob Elliott comments on xenotransplantation in Australia

St Cuthbert's College/ Auckland Grammar Careers Evening
10 June 2009

Olivia O'Donoghue, Production Scientist, presented an outline of her education and work experience prior to joining the team at LCT in 2006, and also an insight into her tasks and responsibilities as they are today. Marilyn Geaney followed this with a presentation giving an overview of LCT as a fully integrated company. Questions were put forward by parents, students and teachers.

Olivia O'Donoghue

Marilyn Geaney

Philip Squire

Living Cell Technologies Ltd
PO Box 23 566
Hunters Corner
Manukau
+64 9 276 2690
lct@lctglobal.com

Rebecca Wilson
Investor and Media Relations
Mob: +61 417 382 931
Tel: +61 3 9866 4722
rwilson@bcg.com.au