Living Cell Technologies Limited

Company Announcement

LCT announces positive DIABECELL® Phase I/IIa trial

26th September, 2012: Sydney, Australia & Auckland, New Zealand – Living Cell Technologies Limited (ASX: LCT; OTCQX: LVCLY) today announced the results of the New Zealand Phase I/IIa clinical trial for DIABECELL, a breakthrough treatment for people with uncontrolled type 1 diabetes. The company also provided a preliminary update on the Argentinian Phase I/IIa trial.

The New Zealand dose-finding trial was led by Dr John Baker at Middlemore Hospital in Auckland and saw 14 patients treated with a single implant of DIABECELL at doses of 5,000, 10,000, 15,000 and 20,000 IEQ/kg (islet equivalents per kilogram of body weight). The trial demonstrated that DIABECELL is a safe and effective treatment which results in:

- a statistically significant reduction in unaware hypoglycaemic events at doses of 5,000 and 10,000 IEQ/Kg
- a trend to reduction in HbA1c
- improvement in patient-reported quality of life.

Whilst the Argentinian Phase I/IIa trial is on-going, an informal analysis of preliminary data confirms the findings of the New Zealand trial while also showing:

- a reduction in HbA1c, insulin dose and unaware hypoglycaemia following two implants at a dose of 5,000 IEQ/Kg each implant
- a reduction in HbA1c, insulin dose and unaware hypoglycaemia following a single implant at a dose of 10,000 IEQ/kg.

The data in the Argentinian Phase I/IIa trial will be more formally analysed and reported through an interim analysis in Q4 of this year.

DIABECELL is owned by the joint venture company Diatranz Otsuka Limited, in which LCT and Otsuka Pharmaceutical Factory both have a 50% interest.

"Unaware hypoglycaemia is very hard on patients and families. Without warning, it may result in a sudden onset of unconsciousness, or convulsions, or even death. It usually means a lower quality of life, a higher risk of complications and an overall shortened life expectancy" said Dr John Baker. "If we can clinically stabilise glucose control and eliminate hypoglycaemic episodes it can significant improve patients' quality of life and improve health outcomes"

"DIABECELL is the first islet transplant treatment that does not require ongoing administration of debilitating immunosuppression drugs," said Professor Bob Elliott, Chief Science and Medical Officer, LCT. "The principal purpose of the New Zealand trial was to confirm the safety of DIABECELL as well as determine the ideal dose for maximal efficacy. We have been successful in achieving both these goals."

The early learnings from the New Zealand phase I/IIa trial led LCT to make a number of improvements to the manufacturing and clinical protocols, and these were taken into the Argentinian Phase I/IIa extension.

"The informal analysis of the data from the Argentinian trials signals that these improvements are taking us ever closer to a world first of a non-immunosuppression requiring cell therapy treatment for type 1 diabetes," says Dr Andrea Grant, Chief Executive, LCT. "We are now readying ourselves for the pivotal trial phase and remain on track to meet our goal of completing the clinical trials of DIABECELL by 2015."

A more detailed summary of the past, current and future clinical trial program for DIABECELL is attached to this announcement and is attached to this statement and available for download on www.lctglobal.com.

About DIABECELL

Diabetes is usually treated with insulin replacement. A serious and potentially fatal complication associated with intensive insulin replacement therapy is unaware hypoglycaemia. Episodes of unaware hypoglycaemia occur when, without associated symptoms or warning, blood glucose levels drop suddenly. Some patients require significant time and resources from specialist healthcare professionals and have a poor prognosis: lower quality of life, more micro vascular and pregnancy complications and shortened life expectancy.

Treatment with DIABECELL involves transplanting pig pancreatic islet cells into a patient's abdomen to boost insulin production and help regulate blood glucose levels. The cells are encapsulated with IMMUPEL™ to prevent the immune system rejecting them as foreign. This proprietary technology ensures the cells can deliver their beneficial effects without the patient requiring immunosuppressant drugs.

DIABECELL is in dose-finding Phase I/IIa clinical trials in Argentina and New Zealand.

For a summary of DIABECELL's clinical trial programme please visit: www.lctglobal.com.

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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.

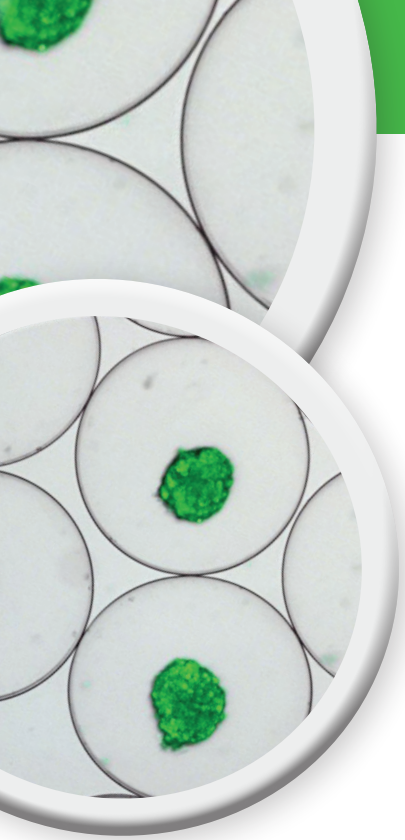
LCT's lead therapeutic candidate DIABECELL® is indicated for the treatment of patients with type 1 diabetes, especially those suffering from life threatening episodes of unaware

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 AUD25m 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



DIABECELL®
Clinical Trials Update

DIABECELL is a breakthrough cell therapy transplant treatment for DIABETES. Living Cell Technologies discovered and developed DIABECELL up to Phase II clinical trials, before transferring ownership to DIATRANZ OTSUKA Limited (DOL); a 50/50 joint venture formed between Living Cell Technologies and Otsuka Pharmaceutical Factory in November 2011. DOL is responsible for the final development and commercialisation of DIABECELL. This update provides the latest results from the recently completed New Zealand Phase I/IIa trial as well as informal analysis of data emerging from the Argentinian Phase I/IIa trial which is still in progress.

The New Zealand Phase I/IIa clinical trial: outline

The trial is an open-label investigation of the safety and effectiveness of DIABECELL® in patients with type 1 diabetes mellitus.

The trial was conducted at the Centre for Clinical Research and Effective Practice, Middlemore Hospital, Auckland, New Zealand by principal investigators - Dr John Baker and Dr David Holland.

A single implant of alginate-encapsulated neonatal porcine islet cells (DIABECELL) was delivered into the patients adomen under general anaesthesia. Patients were implanted with different levels of islet cells: 5,000, 10,000, 15,000 or 20,000 islet equivalents per kilogram of body weight (IEQ/kg)[1]. Only two patients were treated with 20,000 IEQ/kg, whilst the other doses were applied to four patients in each group. A total of 14 patients were enrolled into the trial, all patients completed the trial and all are included in the efficacy and safety evaluations.

Patients were monitored for safety and efficacy endpoints during the baseline period and for 52 weeks post-transplant. Data were collected at site visits, from daily diary cards and periodically using continuous glucose monitoring over a 72 hour period.

A range of safety and efficacy endpoints were assessed and formal statistical analyses were conducted where appropriate. However, due to the small group sizes (n=4 or n=2 patients per treatment group) the ability to show statistically significant effect of treatment is limited.

Main findings from the New Zealand Phase I/IIa trial

Overall, the data are promising with regard to the effectiveness of DIABECELL. The 5,000 and 10,000 IEQ/kg in particular were associated with measures of efficacy in the trial. The 15,000 IEQ/kg and 20,000 IEQ/kg treatment appeared less effective (see Box 1).

Implantation of DIABECELL® in type 1 diabetic patients appears to be safe on the basis of this trial, and the optimal dose appears to be in the range of 5,000 IEQ/kg to 10,000 IEQ/kg.

Further investigation and refinement of the endpoints and measurements through the Argentinian Phase I/IIa will allow a further assessment of the treatment.

[1] An Islet Equivalent (IEQ) is a means of counting islets which differ in size. The number of islets is estimated by mathematically adjusting each islet to a reference size.

Summary of findings in New Zealand Phase I/IIa trial

1. The implant of alginate encapsulated porcine islet cells into type 1 diabetic patients was well tolerated.
2. Reactions to the implantation procedure were noted but these were of low incidence and resolved quickly. No long term reactions were evident.
3. There were 4 **S**erious **A**dverse **E**vents (SAE) related to the transplant one of which was associated with the surgical procedure.
4. Quality of life questionnaires revealed a positive impact of treatment.
5. There was no evidence of xenogeneic infection of patient, partners or persons in close contact with the transplant recipients.
6. The primary endpoint was a reduction in HbA1c[2] compared to baseline. At 52 weeks the 5,000, 10,000 and 20,000 IEQ/kg treatment groups levels were lower than baseline. 4 out of 14 patients had HbA1c levels ⩽7 at the end of the trial compared to 0 of 14 at baseline.
7. A statistically significant improvement in hypoglycaemic events was observed in the 10,000 IEQ/kg treatment group (Figure 1).
8. A statistically significant reduction in the number of unaware hypoglycaemic events was also observed in both the 5,000 and 10,000 IEQ/kg treatment groups (Figure 2).
9. Reductions in insulin use is evident in all treatment groups and group means show marked reductions in the 5,000 and 10,000 IEQ/kg groups.
10. Daily insulin dose calculated as a 4 week average was significantly reduced in the early stages post transplant in the 10,000 IEQ/kg treatment group (Figure 3).

[2] Glycated haemoglobin (HvA1c) ii a clincal measure of the patients average blood glucose concentration over a prolonged period of time.

Figure 1: Four weekly hypoglycaemic event scores: 10,000 IEQkg.

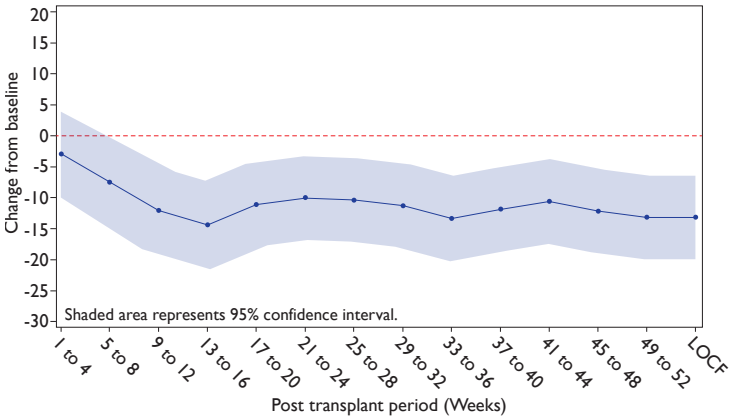


Figure 2:

Four weekly asymptomatic (unaware) hypoglycaemia scores: Group means

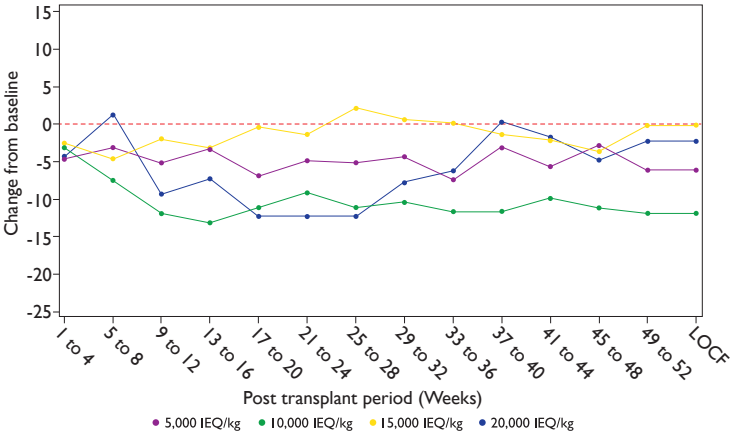
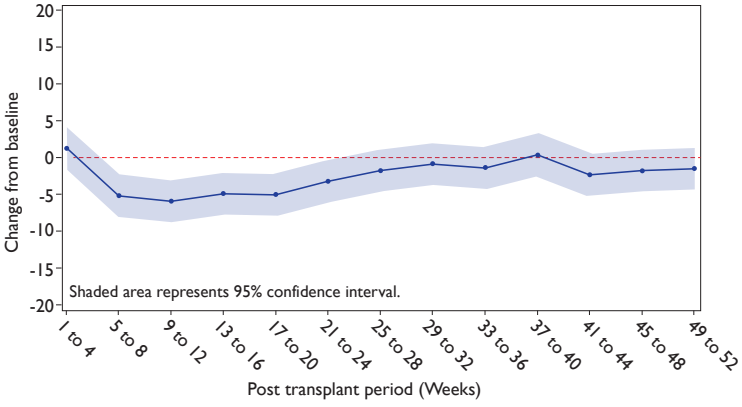


Figure 3: Average four weekly change in insulin dose: 10,000 IEQkg.



Argentina Phase I/IIa trial: outline

Argentina Phase I/IIa trial is an open-label investigation of the safety and effectiveness of DIABECELL in Patients with type 1 diabetes mellitus.

The trial has been underway since August 2011 and is being conducted at the Eva Perón Hospital in San Martín, Argentina by principal investigator Dr Adrian Abalovich, MD.

A total of eight type I diabetic patients were enrolled into the trial. Patients are split into two groups of four. Group one received two implants of 5,000 IEQ/kg and Group two will receive two implants of 10,000 IEQ/kg. Clinical assessments are made over a baseline period prior to first transplant and at four week intervals thereafter. Patients received a second implant 12 weeks following the first and will be assessed for a 52 week period following the second implant.

Alginate-encapsulated neonatal porcine islet cells (DIABECELL) were implanted into the patient's abdomen via laparoscopy under general anaesthesia.

Patients are monitored for safety and efficacy endpoints during the baseline period and will be monitored for 52 weeks post-second-transplant. Data are collected at site visits or from daily diary cards and using continuous glucose monitoring.

A range of safety and efficacy endpoints are being assessed and whilst the trial has not proceeded for long enough to allow an interim statistical analysis, data emerging from the trial allows us to present the following informal observations.

The Argentinian trial differs from the New Zealand trial nine minor modifications were made and the patients received two implants, with the second implant taking place 12 weeks after the first.

The fact that a second implant is made has also provided an opportunity to biopsy the first implant in the patients. We have been able to recover DIABECELL from the site of the first implant and perform histological assessment of the encapsulated islets at the transplant site.

The Argentinian trial is still on going. However, we are able to present in this newsletter an informal analysis of the data emerging from the trial.

Box 2: Data emerging from informal analysis of Argentinian Phase I/IIa trial

1. Two implants of 5,000 IEQ/kg has led to reductions in HbA1c, Insulin dose and unaware hypoglycaemia events at 12 weeks post second implant (24 weeks post first implant). (Table 1).

Table 1: Clinical data in Group 1: 2 implants of 5,000 IEQ/kg

Group1 (N=4)	HbA1c	Insulin dose	Hypoglycaemic events/4w	Unaware HE/4w	Hypo score
Baseline	9.5	63	16.8	13	20.8
12w	7.6	59	25	19.8	23.3
24w	7.9	53	17.3	7.8	7.8

HE = Hypoglycaemic Events

2. A single implant of 10,000 IEQ/kg led to reductions in HbA1c, Insulin dose and unaware hypoglycaemia events at 12 weeks post -implant (Table 2). These reductions were seen both at a group level, as well as in each individual patients recordings (Table 3).

Table 2: Clinical data in Group 2: To date, a single implant of 10,000 IEQ/kg

Group2 (N=4)	HbA1c	Insulin dose	Hypoglycaemic events/4w	Unaware HE/4w	Hypo score
Baseline	8.4	62	22.3	21.5	30.6
12w	6.6	41	19.3	11.8	20.2

HE = Hypoglycaemic Events

3. DIABECELL from the first implant was successfully retrieved by biopsy at the time that the second implant of 5,000 IEQ/kg was made (i.e. 12 weeks post first implant). Histological analysis showed that the islets are expressing both porcine insulin and glucagon (Figure 4).

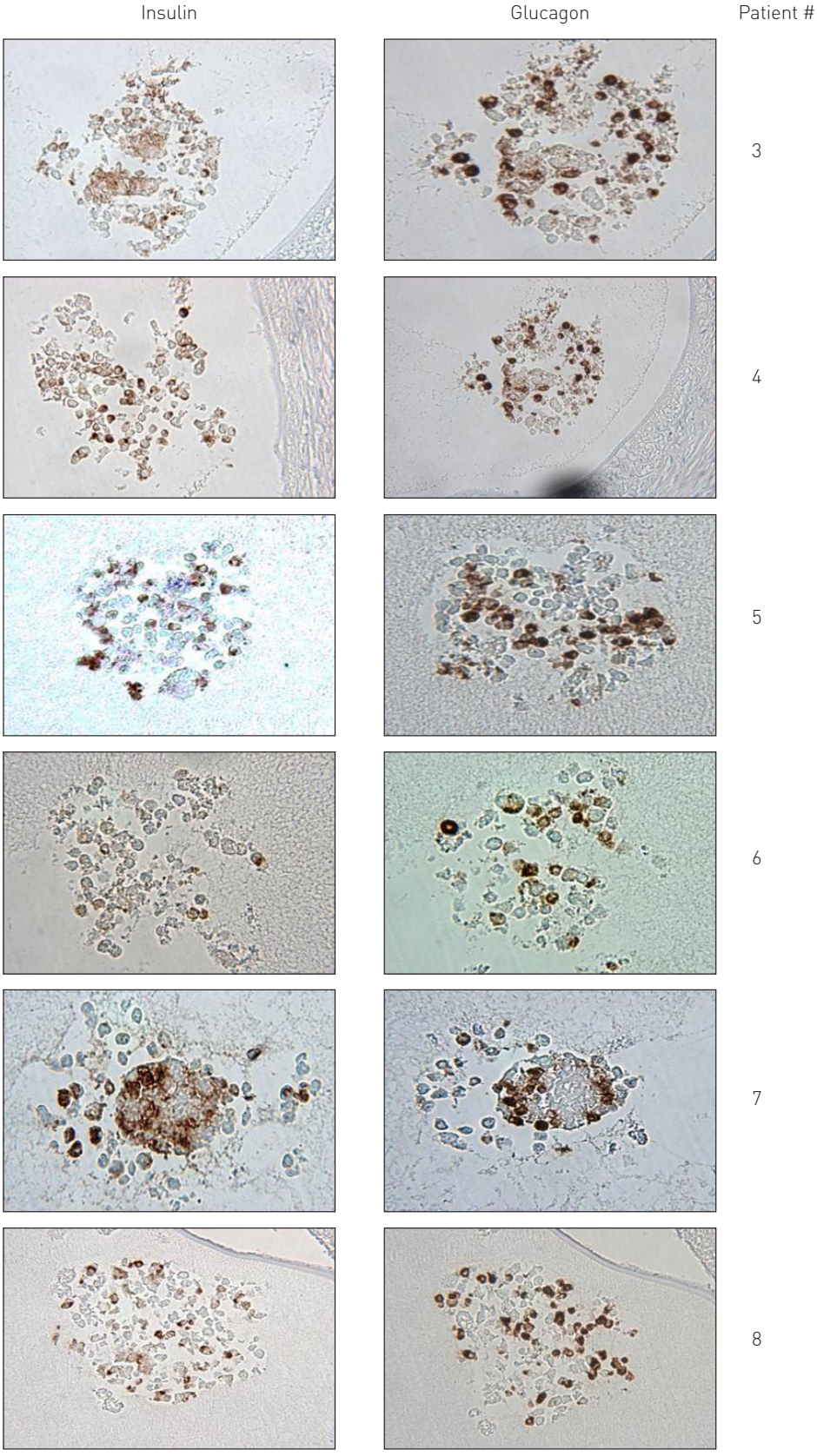
Table 3: Individual patient data from Group 2: To date, a single implant of 10,000 IEQ/kg

	Timing	HbA1c	Insulin dose	Hypoglycaemic events/4w	Unaware HE/4w	Hypo score
Pt5	Baseline 12w	8.6 6.8	27 11	21 27	27 14	31 25
Pt6	Baseline 12w	8.2 6.7	83 58	9 12	6 2	12 5
Pt7	Baseline 12w	8.2 6	79 45	46 30	40 28	61 44
Pt8	Baseline 12w	8.6 6.7	60 48	13 8	13 3	19 7

HE = Hypoglycaemic Events

Figure 4

Microscopic analysis of encapsulated islets explanted from patient biopsies at 12 weeks post first implant when the second implant occurred. Islets were stained for either porcine insulin or porcine glucagon. Brown staining indicates cells expressing the appropriate protein. (Patients 1 & 2 were not biopsied due to technical difficulties) at the time of the recent implant.



Putting it all together – a path to patients and the market

The promising data in the New Zealand Phase I/IIa and emerging from the Argentinian Phase I/IIa trial has enabled us to apply for a Phase IIb trial in Argentina. This trial is designed to confirm the efficacy data that we have seen in the Phase I/IIa trials to date. It will involve 20 patients, all of whom will receive two implants of 10,000 IEQ/kg, with the second implant occurring 12 weeks after the first. It is hoped that we will receive approval to commence this trial in January 2013.

Meanwhile we are planning an interim statistical analysis on the data from the Argentinian Phase I/IIa trial in Q4 of this year. If this interim analysis confirms the strong efficacy effects we have seen to date in this Argentinian trial, then we will seek permission from the Argentinian regulators to amend the Phase IIb trial to a Phase III trial (i.e. pivotal). At the same time, we will apply to NZ's medicines regulatory authority, Medsafe, to include NZ as a centre in this Phase III trial. The Paul Erlich Institute and University of Munich Clinical school have also expressed a keen interest in being included as a third centre in the Phase III clinical study. This latter option will require a separate application to the European medicines safety regulators.

A summary of the clinical trials of DIABECELL performed to date is shown in Table 4, whilst a summary of the future trials is shown in Table 5. Finally, an expected timeline for these trials is shown in Figure 5.

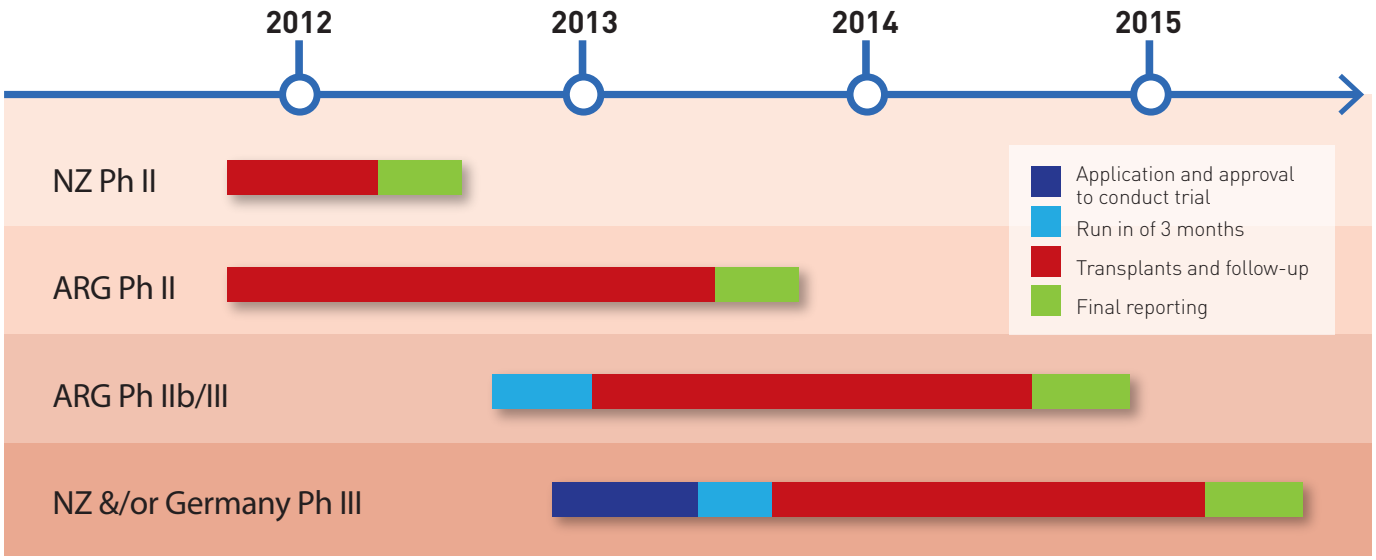


Table 4: Summary of DIABECELL clinical trials performed to date

Location	Phase	# Patients	Dose (IEQ/kg)	# Implants	Follow up (mths)	Main findings	Future data
Russia	I	8	5 or 10	1-2	6-24	Safe, variable insulin dose reduction	N/A
NZ	I/IIa	14	5,10, 15 or 20	1	12	Safe, significant reduction hypoglycaemic events, significant improvement in patient quality of life, trend to HbA1c reduction	hypoglycaemic events, significant improvement in patient quality of life, trend to HbA1c reduction, Two patient extension of 20,000 IEQ/kg. Implants will be performed during Q4 2012; report expected Q1 2014
Argentina	I/IIa	8	5 or10	2	12	Informal analysis reveals reductions in HbA1c, unaware hypoglycaemia and insulin dose	Interim analysis will be performed during Q4 2012 with final report expected Q3 2013

Table 5: Future trials for DIABECELL planned

Location	Phase	# Patients	Dose (IEQ/kg)	# Implants	Follow up (mths)	Target Product Profile	Timing
Argentina	IIb/III*	15	10	2	12	Informal analysis reveals reductions in HbA1c, insulin dose	Approval expected Q4 2012. Implants expected to complete Q2 2013. Follow up & report by Q1 2015
NZ and/or Germany	III	10					**Approval hoped for Q2 2013. Implants complete Q4 2013. Follow up & report Q1 2015

*If the interim analysis of the Argentinian Phase I/IIa trial provides sufficient confidence in the Target Product Profile of DIABECELL then we will amend the Argentinian Phase IIb trial and upgrade its status to Phase III.

** We will seek approval to conduct the NZ and/or Germany Phase III trial provided the interim analysis of the Argentinian Phase I/IIa trial gives a high level of confidence in the target product profile of DIABECELL.

Summary

Despite advances in diabetes care, many type 1 diabetics (T1D) cannot achieve adequate metabolic control without experiencing repeated episodes of severe hypoglycemia. Allogenic[2] transplantation of human pancreatic islet cells has been shown to be successful in enabling patients to achieve either insulin independence or improved control with a reduction in severe or unaware hypoglycemia. However, human islet transplantation is currently reserved for only a select few patients who experience extremely poor diabetes control and quality of life.

There are two principle reasons for this, the scarce supply of suitable pancreatic islet cell donors and the fact that the therapy requires intensive treatment with immunosuppressive drugs, which can cause debilitating side effects.

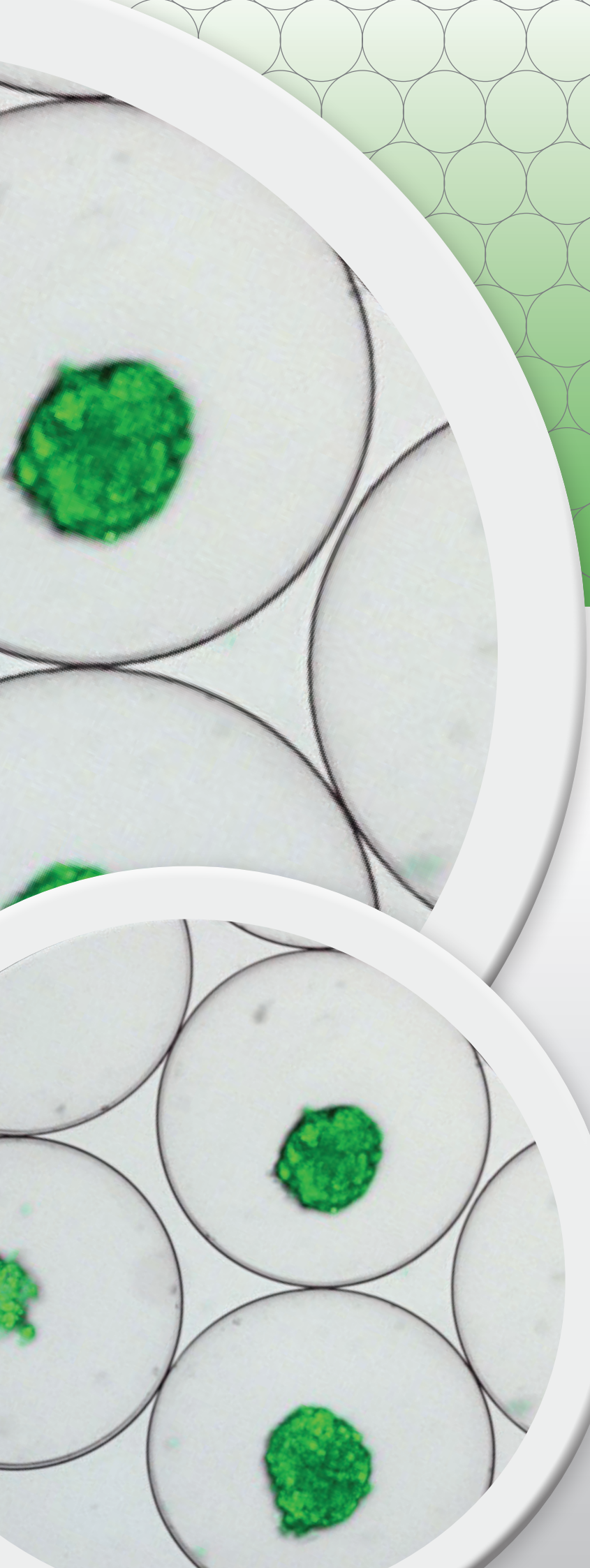
By using pigs for the cell supply, and by encapsulating the cells to protect them from the immune system DIABECELL has the potential to overcome both these shortcomings of human islet transplantation.

None the less, human islet transplantation provides a useful guide of what will be a clinically meaningful efficacy for DIABECELL for regulators, most importantly patients. A recent paper in the American Journal of Transplantation reviewed the data from 347 allogeneic islet transplant recipients, using data from the Collaborative Islet Transplant Registry (CITR)[3]. This paper, together with FDA published guidelines[4] on allogeneic pancreatic islet cell products conclude that a single-arm, open-label trial may be able to provide substantial evidence of efficacy and safety in subjects with metabolically unstable type 1 diabetes.

In this design, a historical control arm may be used. Both papers also conclude that a composite endpoint consisting of HbA1c ⩽ 6.5% and a reduction in hypoglycaemic events at 1 yr post transplant is a clinically meaningful achievement for both regulators and patients.

The data emerging for DIABECELL from the NZ and Argentinian Phase I/IIa trials gives us confidence that these clinical outcomes are within reach. We are still on track to be well into pivotal Phase III trials during 2013, with the expectation that we will have sufficient data to submit to the NZ medicines safety authority at the end of 2015.

[2] Allogenic is the term used to describe the transfer of cells or organs from one patient to another.
[3] Tiwari et al. Islet Cell Transplantation in Type 1 Diabetes: An Analysis of Efficacy Outcomes and Considerations for Trial Designs (2012) American Journal of Transplantation; 12: 1898–1907
[4] Guidance for Industry: Considerations for Allogeneic Pancreatic Islet Cell Products. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, (2009) http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.
[5] Kaitin (2010) Deconstructing the Drug Development Process: The New Face of Innovation, Clinical pharmacology & Therapeutics, 87 (3): 356-361



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