



Treating Diabetes - DiabeCell[®]

Living Cell Technologies Ltd (ASX:LCT) is a cell therapy company commercialising live cell transplants for major life-threatening diseases. The ASX-listed, vertically integrated company focuses on developing treatments where healthy living cells are injected into patients to replace or repair damaged tissue without the use of toxic drugs to prevent rejection.

DiabeCell[®] - Type 1 Diabetes Mellitus

- A porcine pancreatic islet cell product for the treatment of insulin-dependent diabetes.
- The insulin producing islets are coated in an alginate gel (biocapsule) to prevent rejection by the body's immune system and transplanted into the peritoneum (abdominal cavity lining) to regulate blood glucose levels.
- The encapsulated cells do not require the use of immunosuppressant drugs.
- Status: Approved for Phase I/IIa clinical trial.

Health Facts

Diabetes is a chronic disease characterized by high blood glucose levels resulting from insufficient insulin. A build-up of glucose in the blood deprives the cells of energy and affects eye, kidney, nerve or heart functioning. Regular treatment consists of lifelong daily insulin injections, regular blood glucose level tests, healthy eating plans and physical activity.

Type 1 diabetes occurs when the pancreas gland no longer produces the insulin needed.

Type 2 diabetes is the most common form of diabetes, known as the 'lifestyle disease'. It occurs when the body requires higher than usual amounts of insulin and ultimately fails to produce a sufficient amount.

Statistics

- 4th leading cause of death in the developed world
- 23.7m people worldwide expected to suffer Type 1 diabetes by 2010
- Direct health costs to Australian community well over \$100m p/a
- Up to 12 per cent of cardiovascular deaths in Asia-Pacific are due to diabetes
- Initial sales of DiabeCell[®] expected in 2011/12.

Sources:

1. Frost & Sullivan, Organ Transplant Markets
2. International Diabetes Federation
3. Juvenile Diabetes Research Foundation
4. McCarty et al; The rise and rise of diabetes in Australia
5. Asia-Pacific Cohort Studies Collaboration Report

Developments

- Approval to proceed for a Phase I/IIa clinical trial in New Zealand in 2007 - pending regional ethics approval.
- Approved for a Phase I/IIa clinical trial in Russia designed according to FDA guidelines and monitored by a US contract research organisation.
- Successful safety / efficacy of DiabeCell[®] in pre-clinical small and large animal models.
- Long-term safety and function of islet cells monitored 10 years post transplant in a diabetic and published in an international journal.

Clinical Trial Design

- LCT's proposal for the human clinical trial of DiabeCell[®] in Russia will include six type 1 (insulin-dependent) diabetics.
- The candidates must have had type 1 diabetes for at least 10 years with no other complications and provide full consent for follow-up monitoring.
- The patients will receive an initial transplant (a simple injection of encapsulated islets into the peritoneal cavity) followed by a second transplant six months later. The procedure is minimally invasive and administered through a laparoscope.

Route to Market

The company's commercialisation strategy is to progress DiabeCell[®] through clinical trials and then offer transplants to patients through existing cell therapy centres. LCT will continue to pursue discussions with large co-development and marketing partners to assist in expanded market penetration and geographical representation for the manufacture and sale of DiabeCell[®].

Further information

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