

LCT celebrates xenotransplantation reversal

LIVING Cell Technologies says it may expand its clinical trial programs into Australia, following the National Health and Medical Research Council's decision to lift its long-standing ban on xenotransplantation research.

Nick Evans

The NHMRC announced this morning (Dec 10 2009) it will allow clinical trials involving animal to human transplantation, once regulatory and surveillance frameworks are in place.

NHMRC chairman Professor Michael Good said the council, in making its decision, had noted the developments in science and technology since 2004, in particular evidence relating to the risks of transmission of animal viruses.

"After careful consideration, the council is of the view that, although there is a wide range of community views on the topic, xenotransplantation research was acceptable in Australia when there are robust regulations in place," he said.

"Council has taken into account a range of issues, including the risk of viral transmission and the evidence available on the safety of the therapy for individuals and the wider community."

LCT chief executive Dr Paul Tan said the company welcomed the NHMRC decision.

"This is in keeping with recent scientific data and the increasing acceptance of current international guidelines for the safe use of animal tissue to treat human disease," he said.

"This decision opens up significant opportunities not only for LCT, but for the wider medical science community and people with life-threatening diseases."

LCT has harshly criticised the refusal of Australian regulators to allow xenotransplantation trials, and has been forced to conduct early human studies of its Diabecell treatment – which implants encapsulated pig islet cells into diabetics – in Russia and more recently in New Zealand.

"LCT is already involved in an exciting pilot project in animals in Australia, with the Bionic Ear Institute in Melbourne involving our NTCELL, and we look forward to having discussions with regulatory authorities around protocols for bringing our platform technologies and trials to Australia," Tan said.

NHMRC chief executive Professor Warwick Anderson said human trials may be some time away, however.

"The process for testing new procedures through clinical trials can take many years and involve several phases," he said.

"Trials would be able to proceed once ethical approval has been given and the Therapeutic Goods Administration has implemented a robust framework to regulate clinical trials involving xenotransplantation.

"Further the NHMRC, using the advice of its Australian Health Ethics Committee and Animal Welfare Committee, would now develop guidance for researchers and ethics committees involved in animal-to-human studies."



*LCT CEO Paul Tan and
Medical Director Bob Elliot*