



Newsletter

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January 2021

Hope for early phase clinical trial

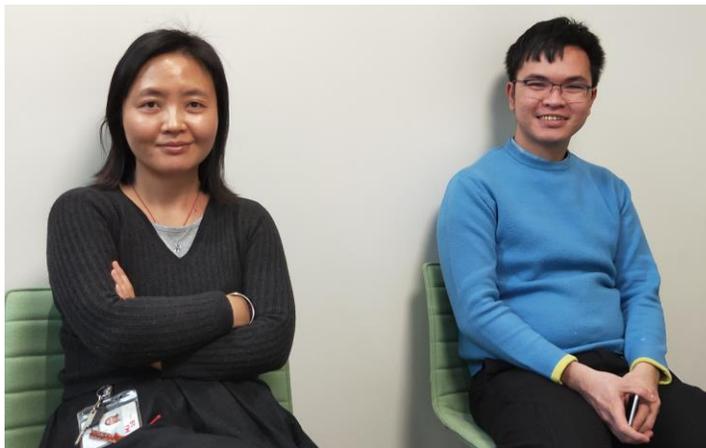
It is hoped that pre-clinical experiments at the University of Technology (UTS) will be completed during the coming year, so that an application can be made to obtain regulatory approval to conduct an early phase clinical trial.

Despite the setbacks caused by COVID-19, the Australian Foundation for Diabetes Research (AFDR) and the Israeli company Kadimastem Ltd continued their collaboration over the past year to develop a cell therapy for type 1 diabetes.

The Israeli company has been sending stem cell derived insulin-producing cells to Sydney, and the AFDR has been sending 3D printed scaffolds for the cells to Israel. The cells are placed in microcapsules made from seaweed, and then implanted under the skin of diabetic mice to test the therapy.

The primary aim of this trial will be to examine the safety of implanting a bioengineered device in diabetic humans. A secondary aim will be to determine if human insulin can be produced from the cells in the graft. The small number of cells being implanted in this initial trial will make it unlikely there will be any major effect on the amount of insulin recipients will need to administer daily to control blood glucose levels.

During 2020, the Sydney base for the preclinical studies changed from the University of Sydney (USYD) to the University of Technology Sydney (UTS). This was necessitated because of diminishing laboratory space at USYD. The researchers conducting the experiments at UTS are the post-doctoral fellow Dr Felix Dang, and Associate Professor Hui Chen from the School of Life Sciences.



l to r. Associate Professor Hui Chen and Dr Felix Dang at a rare face-to-face research meeting at UTS during 2020. Most meetings were held by zoom because of COVID-19 restrictions.

Support from the National Stem Cell Foundation of Australia



The National Stem Cell Foundation of Australia (NSCFA) has been providing major support to the AFDR during the past year. Donors that would normally provide funds to the AFDR have instead been giving these to the NSCFA, which has been matching the donations. This means the AFDR has been receiving twice the funds it might normally receive. Donors continue to receive tax deductible receipts, since the NSCFA like the AFDR is registered as a Level 1 Deductible Gift Recipient. Details can be found [here](#).

The progress of the research project being conducted at UTS is reported regularly to the NSCFA by the AFDR Director, Professor Bernie Tuch. "We are happy to have been notified that the NSCFA Board is pleased with our progress," said Professor Tuch.



Donor Mark Jeries took time out to see first-hand what the Israeli human insulin-producing cells look like. He is pointing to a computer image of a cluster of such cells before they are encapsulated.



Tissue Engineering publication

The proof-of-concept of using a bioengineered device for the treatment of type 1 diabetes was established in the laboratories of The University of Sydney over the past four years. This proof-of-concept entailed using mouse rather than human insulin-producing cells. The researcher who carried out the majority of this extensive work was Dr Auvro Mridha, whose contribution is recognised as first author of the manuscript that describes this work. The paper was published [on-line](#) in November 2020 in the peer reviewed journal *Tissue Engineering*.



Presentation at Conferences

Professor Bernie Tuch attended the Annual Scientific Meeting of the Australasian Diabetes Congress during November and participated in the Bench to Bedside Symposium on Stem Cells. His address was *Immunosuppression Free Transplantation of Stem Cell Derived Beta Cells*. He gave an overview of progress being made worldwide and included data from the Bioengineered Diabetes Therapy Project the AFDR is supporting.



Similarly, Professor Tuch presented at the annual meeting of AusBiotech, held by zoom in October. His talk on *Bioengineered Diabetes Therapy* was part of the session on *Australian Developments in Regenerative Medicine*.



Research to explore effects of infra-red on immune response

The AFDR was successful in its application for a grant which will allow a senior researcher to explore the effectiveness of using infra-red light to cause localised release of anti-rejection agents from microcapsules containing insulin-producing cells. "If successful," Professor Tuch said, "this strategy will enhance the capability of insulin-producing cells seeded in our bioengineered device to normalise blood sugar levels of diabetic recipients."

The Innovative Grant from the Juvenile Diabetes Research Foundation is entitled *Luminescent nanoparticles for controlled localised release of immunomodulatory agents*. This international, peer reviewed grant provides funds for one year towards this innovative research.



Gandel Philanthropy

We have been fortunate in being supported by the charitable Foundation *Gandel Philanthropy* (GP), for our Bioengineered Diabetes Therapy Project, for a period of two years. The goal of the Project is to demonstrate the safety and efficacy of transplanting human insulin-producing cells, derived from Israel, in diabetic animals. The application to GP was made under the division that promotes relationships between Australia and Israel.

In advising the AFDR of the success of its application for funding, Mr Vedran Drakulic, OAM, and CEO of Gandel Philanthropy said that "It is a pleasure to be among your current supporters".



Patent Examination

During the last year, we heard back from the expert examiners in the USA and Europe on our patent *Cell Associated Scaffolds for Delivery of Agents*, which describes the bioengineered device we are using.

With the assistance of our patent attorney at LegalVison, we responded to the comments, making claim that several matters were both novel and inventive. The granting of a patent should provide protection to the AFDR as it deals with other entities around the world interested in working with it to deliver a commercial cell therapy for treatment of type 1 diabetes.



Australian Foundation for Diabetes Research

MAKING A DONATION

There are three ways you can make a donation to support the *Bioengineered Diabetes Therapy Project*, being conducted by the AFDR:

1: Via Credit Card

2: Via cheque/money order payable to the *Australian Foundation for Diabetes Research*
PO Box 821, Maroubra NSW 2031

OR

**National Stem Cell Foundation of Australia (NSCFA)* PO Box 140, McCrae VIC 3938

3. Via Bank Transfer to the *Australian Foundation for Diabetes Research*:
BSB 062 230, Account Number 1027 3887

OR

**National Stem Cell Foundation of Australia*
BSB 083 266, Account Number 12305 0040

* The NSCFA has an arrangement with the AFDR to match \$ for \$ for donations ≥ \$500. Thus, if you donate \$1000 to the NSCFA for the Diabetes Project, the NSCFA will give the AFDR \$2000.

Via Credit card:

Amount:

- \$50 \$100 \$200 - 1 wk supply of mice
- \$400 = 1 wk supply of chemicals
- \$500 \$1000
- \$2300 = 1 wk salary Research personnel
- Other \$.....

Visa Mastercard

Name on card

.....

Card number ____ / ____ / ____ / ____

Expiry/..... Validation number ____

MAKING A BEQUEST

I give to the Australian Foundation for Diabetes Research:

- the sum of _____,
- the following assets in my estate: _____, or
- ___ percent of my estate, free from all duties thereon.

* When drafting your will, please select only the relevant alternative.

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