Press Release
Loxegen
16 February 2024

Loxegen nanoparticle gene therapy for Cystic Fibrosis (*CF*) awarded prestigious MRFF grant.

Loxegen to merge with Respien and list on the ASX.

Loxegen is pleased to announce that its nanoparticle gene therapy for CF has been awarded an A$1.5 million grant by the Medical Research Future Fund involving a highly competitive process. With additional infrastructure and resources being contributed by the participants the result will be a A$3.0 million plus program. Loxegen will continue to own all the IP associated with the particles.

The team is a partnership between between:

1) **Academic organisations:** (UQ School of Biomedical Sciences, UQ Centre for Advanced Imaging and the Australian Institute of Biosciences and Nanotechnology), **research institutions** (Murdoch Childrens Research Institute and its network of clinicians);

2) **Australian Biotech** company **Loxegen:** and its CEO (MRFF partner and consumer AI Andrew Venables):

3) **Consumer groups:** Cystic Fibrosis Community Care [CFCC] and Cystic Fibrosis South Australia [CFSA]; and

4) **Consumers:** Katherine Kaspar [Chairwoman CFCC], Gen Handley [consumer SA] and Bryson Vaughan [consumer SA]).

CFCC and CFSA have previously been involved in this far-sighted project and provided funding to support generation of some of the preliminary data included in the application.

The funding will allow for further optimisation, characterisation and validation of particles, selection of final product to take to clinical trials using cutting edge CF models, such as CF induced stem cells and animal models. It will also involve characterisation of its pulmonary pharmacokinetics and kinetics/pathways of lung clearance.

Andrew Venables, CEO of Loxegen said:

'As the parent of a child with Cystic Fibrosis I can attest that CF is a terrible disease that shortens patients' lives and involves a very high treatment burden and low quality of life. Loxegen is honoured to be associated with this award and these outstanding academic institutions, charities and high-profile participants. This will advance our already strong body of data that supports this approach as a promising viable alternative for lung gene therapy.

The award is timely as it will add credibility to our project and support our current capital raising activities. Gene therapies are attracting a lot of attention in the US with premium pricing in public markets. There are presently no viable gene therapies in Australia that will allow investors to gain exposure to this hotly sought after asset type.

Further funding will also allow us to explore the application of this therapy to Alpha 1 antitrypsin deficiency, another fatal disease.'

About Loxegen

Loxegen is a Melbourne based biotech company developing a novel polymeric non-viral nanoparticle gene therapy involving essential amino acids that self-assemble with (any) plasmid DNA and are coated in a special protective coating. The particles will be nebulised to the lung, thereby delivering a working copy of the CF gene to cells of the lungs of patients.

Loxegen has already demonstrated efficacy, including return of CF function, in numerous cell and animal models, including primary CF cells, CRISPR modified CF cells and mice. It has shown that its particles are stable, including after being nebulised and can move through CF mucus.

Loxegen has signed a Term Sheet with Respien Pty Ltd with a view to a merger and subsequent ASX listing. Respien has phase 3 ready and phase 1 ready assets comprising a bacterial vaccine and an anti-inflammatory, both of which have application for the major causes of lung damage in CF and COPD. Respien, in turn, has subsequently also signed a Terms Agreement purchase an anti-infective from a US company that has been developed with substantial funding from the US Cystic Fibrosis Foundation, the US National Institute of Health and private investors.

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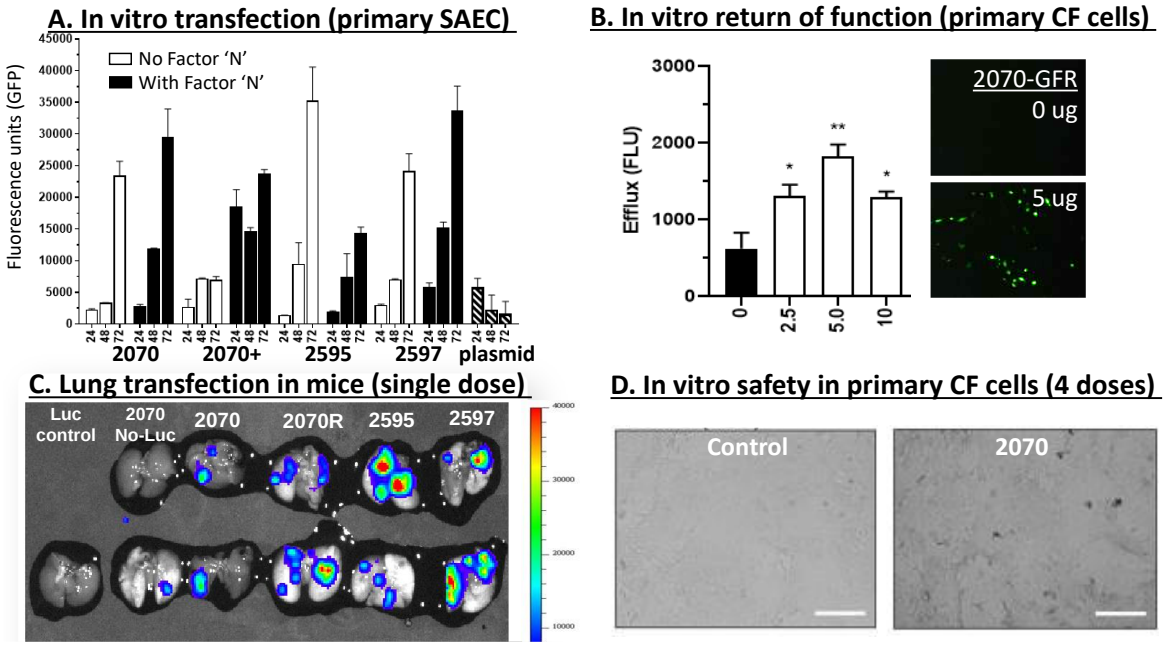

Fig 1. *Proof of concept data with nanoparticles (NPs) prepared from different peptides (2070, 2070+R, 2595, 2597).* ***(A)*** *In vitro transfection efficiency of GFP-NPs in primary small airway epithelial cells with and without 'factor N' 1-3 days after dosing.* ***(B)*** *CFTR 'return of function' halide efflux study in primary CF cells (N1303K mutation) after exposure to one of 3 different NP doses (0-10 ug CFTR DNA). Confocal microscope image of cells transfected with 5 ug 2070-GFR NP.* ***(C)*** *In vivo transfection of 4 different NPs in mice 2 days after a single 70 ug instillation of Luciferase-NP to the lungs (n=2).* ***(D)*** *Morphology (10x) of primary CF cells after exposure to 70 ug CFTR-NP once every day for 4 days.*