Exosome Biosciences

Developing novel pro-regenerative and anti-fibrotic exosome therapies

We have developed a unique platform technology to produce novel exosome therapies derived from human amniotic epithelial cells

Exosomes are nanosized vesicles released by all cell types, including stem cells. Their cargo include proteins, RNA and cytokines which reflect the intracellular contents of their donor cells.

Our exosomes are derived from human placental amniotic epithelial cells (hAECs), and exhibit potent immuno-modulatory, anti-inflammatory, anti-fibrotic and pro-regenerative effects. Our novel hAEC exosome platform is highly effective in pre-clinical models over a range of conditions including bronchopulmonary dysplasia, asthma and stroke, as well as pulmonary, liver and kidney fibrosis.

Advantages of Exosome BioSciences' novel hAEC-derived exosome therapy

- Can be manufactured at scale for a fraction of the cost of hAECs
- First-in-class regenerative medicine platform
- 30-fold more exosomes can be extracted from hAECs compared to MSCs
- Simplified cold chain logistics, storage and handling
- Cell-derived, providing clinicians with a product that is off-the-shelf and easy to use
- Pathway to scalable GMP manufacturing

Key data

Exosome BioSciences' novel platform show promising results in numerous preclinical models of BPD, asthma, kidney/liver fibrosis, and stroke. In vivo studies in lung disease models (Fig 1, 2) show that a single intranasal dose of exosomes reduces pulmonary fibrosis, and activates bronchioalveolar stem cells and type 2 alveolar cells for pro-regenerative effects. hAEC-EVs are also physically distinct (Fig 3), with a significant degree of homogeneity of the CD9 Tetraspanin.

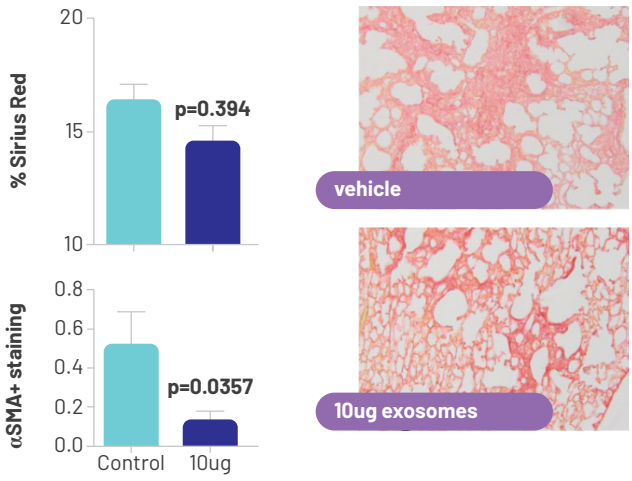

Figure 1. *Amniotic exosomes reverse lung inflammation and fibrosis in a mouse model of lung fibrosis, demonstrated by a reduction of activated myofibroblasts (αSMA positive) and collagen deposition in the lungs (Sirius Red).*

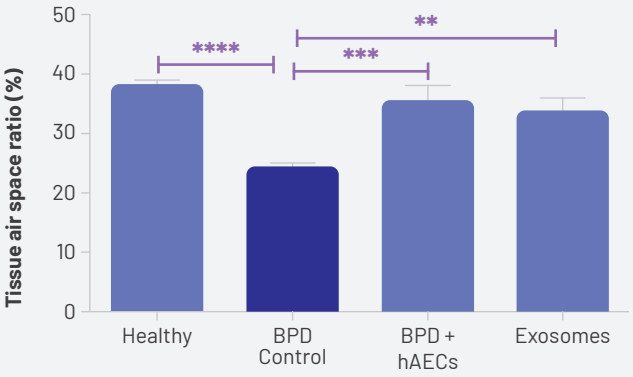

Figure 2. *Exosomes reverse alveolar simplification in a BPD mouse model*

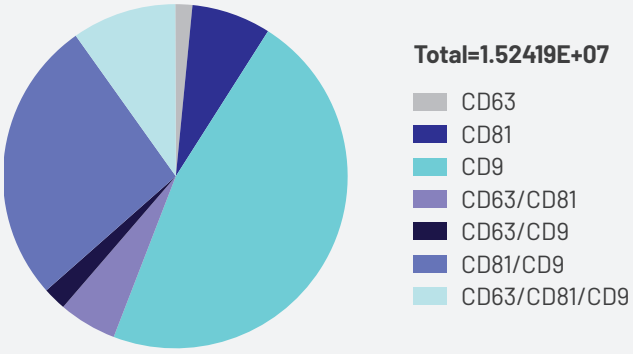

Figure 3. *Tetraspanin co-localisation analysis, hAEC-EVs are classified as carrying either a single, double or triple tetraspanin combination.*

Development status

Exosome BioSciences is currently preparing for a clinical trial which would provide:

- Manufacturing scale-up capacity > 100L
- Clear regulatory pathway
- Clinical data for the platform

Exosome BioSciences is seeking a venture or commercial partner for continued development of the platform.

IP position

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Granted in Australia, US, Europe, China, Singapore and Japan; Allowed in Canada; Entered into National Phase in South Korea.

CSO – Professor Rebecca Lim
Prof. Lim of Hudson Institute is the founder of the program, and is responsible for research and manufacturing.

CMO – Professor Gregory Moore
Prof. Moore is a Monash Health clinician leading the clinical development of the platform.

Clinical Trial Lead – Dr. Charlotte Keung
Dr. Keung is a Monash Health clinician responsible for leading clinical trials.

Directors and BD Lead

Mr. Robert Merriel and Professor Eric Morand are directors of Exosome BioSciences.

Ms. Carmela Monger leads business development and commercialisation of Exosome BioSciences' platform.

Funding

Exosome BioSciences was recently awarded a $1.5m grant from CUREator to develop novel therapies. CUREator is an Australian biotech incubator delivered by Brandon BioCatalyst and the Australian Federal Government's Medical Research Future Fund.

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