REGENASOME Pty Ltd

Exosomes from amniotic epithelial cells for the treatment of fibrosis

ABOUT US

Regenasome Pty Ltd is a Melbourne-based company developing a unique exosome therapy platform based on human amniotic epithelial stem cells founded by Hudson Institute and Monash University. Our exosomes are first-in-class with demonstrated potent anti-fibrotic, pro-regenerative properties.

- **Therapy area:** fibrotic and lung diseases such as Idiopathic Pulmonary Fibrosis (IPF)
- **Stage:** late preclinical
- **Development plan:** rapid human proof-of-concept: 2 years to end of phase 1
- **Track record:** leverages founder expertise in the clinical development of allogeneic hAEC stem cells
- **Manufacture:** reproducible, low-cost cell-free
- **Team:** E. Wallace, R. Lim, D. Chambers

THE TECHNOLOGY

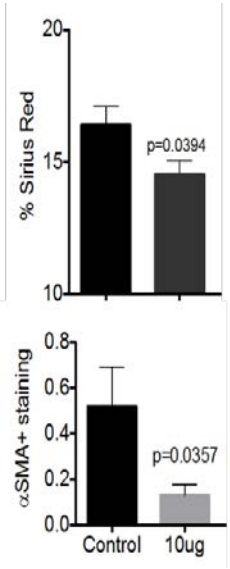
Exosomes are nanosized vesicles released by all cell types, including stem cells. They contain 'cargo' such as proteins, RNA and cytokines which reflect the intracellular contents of their donor cell. Our exosomes are derived from our proprietary bank of human placental amniotic epithelial stem cells (hAECs) and exhibit potent immuno-modulatory, anti-fibrotic and pro-regenerative effects. In addition, our exosomes are highly effective over a range of conditions including IPF, other lung disease, liver and kidney fibrosis. They also have unique production advantages and can be isolated, purified, frozen, lyophilized, packaged and distributed like a standard drug product. Our first product is being developed as a regenerative and anti-fibrotic therapy for IPF.

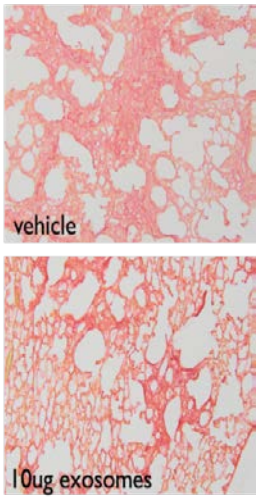
MARKET

Due to their utility for a range of indications, exosomes have the potential to be the next major biotech breakthrough. The global exosomes market size is expected to reach USD 2.28 billion by 2030 exhibiting a CAGR of 18.8%, according to a report by Grand View Research, Inc. Idiopathic Pulmonary Fibrosis (IPF) is an incurable fatal disease with a mean survival of only 3-5 years. The global IPF treatment market is expected to reach USD 4.6 billion by 2023. Worldwide, IPF affects 13 to 20 out of every 100,000 people.

RESEARCH RESULTS

Our exosomes have been tested and shown promising results in numerous models of diseases including IPF, asthma, kidney, liver fibrosis, and stroke.

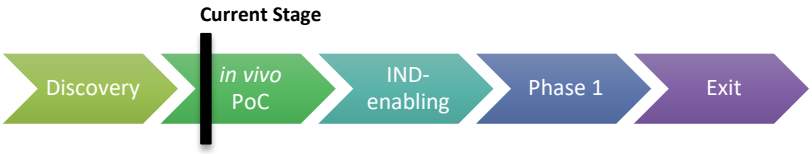




In vivo studies in a range of lung disease models show that a single intranasal dose of the exosomes reduces pulmonary fibrosis, has direct pro-regenerative effects by activation of bronchioalveolar stem cells and type 2 alveolar cells. They also perform better than Pirfenidone in reducing myofibroblast deposition and lung fibroblast collagen production.
They also increase phagocytic activity of macrophages, suppress T cell proliferation and promote a predominant regulatory T cell phenotype.

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

DEVELOPMENT PLAN



ADVANTAGES AND RESEARCH STRENGTHS

- Proprietary exosome therapy with regenerative effects
- Pathway to scalable GMP manufacture
- Greater than 30-fold more exosomes from hAECs than MSCs
- Off-the-shelf, easy to use cell-derived product, administered like a standard drug
- Clinical trial capacity with experienced physicians
- Compelling biological validation in various fibrosis indications including IPF
- Strong expertise in hAECs
- Multi-disciplinary team – biology experts, clinicians
- Extensive tools (screens, models) and expertise to deliver
- Large market with recognised unmet needs
- IP protection

WHAT WE ARE LOOKING FOR:

Regenasome is seeking to raise a Series A of USD10m to achieve the following milestones:

- Exosome production, characterization and validation to enable full preclinical package including biodistribution and toxicity study
- Develop scalable GMP manufacturing of amniotic exosomes
- Phase 1b/2a clinical trial

INTELLECTUAL PROPERTY

Entered into National Phase in Australia, USA, Europe, China, Japan, South Korea, Thailand, Vietnam, Malaysia, Philippines, India, Singapore, Canada, Indonesia based on PCT/AU2016/050468 on method of treatment using hAEC-derived exosomes.

RELATED PUBLICATIONS

Amnion Epithelial Cell-Derived Exosomes Restrict Lung Injury and Enhance Endogenous Lung Repair, Tan J *et al.*, 2018 *Sci Trans Med*.

To Protect and to Preserve: Novel Preservation Strategies for Extracellular Vesicles, Kusuma GD *et al.*, 2018 *Front Pharmacol.*

The Human Amnion Epithelial Cell Secretome Decreases Hepatic Fibrosis in Mice with Chronic Liver Fibrosis, Alhomrani M *et al.*, 2017 *Front Pharmacol.*

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