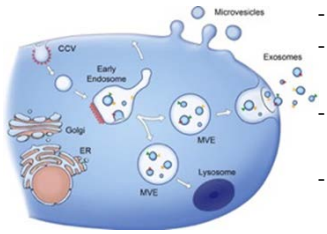
HUDSON INSTITUTE OF MEDICAL RESEARCH

COMMERCIALISATION OPPORTUNITY

Exosome Therapy – a cell-free approach to regenerative medicine

Background: What's an Exosome?

Exosomes are nanosized vesicles released by all cell types, including stem cells. Exosomes contain 'cargo' such as proteins, RNA and cytokines which reflect the intracellular contents of their donor cell. Dr Lim, and others, have found that exosome treatment is highly effective in numerous fibrotic disease models (e.g. liver and lung disease). The amniotic exosomes are derived from human placental amniotic epithelial stem cells (hAECs) which Dr Lim has studied for over a decade. Amniotic exosomes exhibit immuno-modulatory, anti-fibrotic and pro-regenerative effects. Amniotic exosomes have unique production advantages and can be isolated, purified, frozen, lyophilized, packaged and distributed like a standard drug product, similar to FDA-approved liposome therapies.

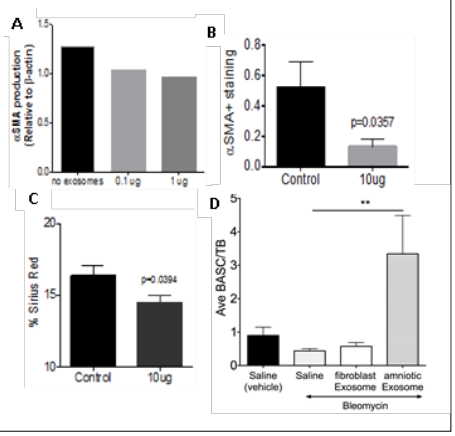


Schematic of exosome release

- Size of vesicle 40-100nm
- Found in blood, serum, urine and breast milk
- All cells export exosomes, and properties reflect the donor cell
- Produced in abundant amounts for cost effective processing, purification and easy storage

Key Data

Amniotic exosomes reduced pulmonary myofibroblast activation *in vitro* and collagen deposition *in vivo*. Bronchoalveolar stem cells were ~3-6 fold more abundant in bleomycin-challenged mice treated with amniotic exosomes. In the carbon tetrachloride mouse model of NASH exosome therapy ameliorates hepatic fibrosis (collagen deposition, data not shown).



Advantages and research strengths

- Proprietary exosome therapy with regenerative effects
- Pathway to scalable GMP manufacture
- Off-the-shelf, easy to use cell-derived product, administered like a standard drug
- Pre-clinical evaluation in pulmonary and liver disease models
- Clinical trial capacity with experienced physicians

IP position

Method of use patent with priority date 12-6-2015

Market

Platform Technology

Exosome therapy is an exciting new field in biotechnology. The first exosome companies were established in 2015 and attracted a combined total of US$120M investment. Due to their wide therapeutic utility - in both diagnostics and therapeutics - and for diverse indications, exosomes have the potential to be the next major biotech breakthrough. The Hudson exosome technology is uniquely positioned from competitors as they are: 1) of amniotic origin and 2) target fibrotic indications. The commercial potential of exosomes is equivalent to the regenerative stem cell therapies as exosomes show pre-clinical efficacy comparable to stem cells, but have far superior drug product-like qualities.

Idiopathic Pulmonary Fibrosis (IPF) and liver fibrosis (non alcoholic Steatohepatisis, NASH)

IPF is an incurable fatal disease with a mean survival of only 3-5 years. In the EU and USA ~60–70,000 new patients are diagnosed each year. The current estimated market opportunity for IPF is $2B p.a. NASH is linked to obesity and affects 2-5% (6M+) Americans. It is characterised by fat deposition and inflammation in the liver and is now a leading cause of liver transplants and described as a global epidemic. The potential market for NASH is $1-2B p.a. by 2020. Exosome therapy could be an adjunct to approved NASH and IPF drugs, with regenerative benefit to halt further deterioration.

Opportunity

Hudson welcomes opportunities for co-investment or collaboration. We are currently undertaking further pre-clinical validation and process expansion with the CSIRO to take this technology to the next level. Hudson has registered a phase1b 15 patient study of hAECs for compensated liver cirrhosis at Monash Health due to commence soon.

For further information

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