A partnership between:

MONASH University | HUDSON INSTITUTE OF MEDICAL RESEARCH

COMMERCIALISATION OPPORTUNITY

Exosome Therapy – a cell-free approach to regenerative medicine

Clinical Need

Current stem cell therapies are limited by a number of risks associated with their clinical use, and by inconsistent cell production, efficacy based on health of 'master donor' and, by high costs of manufacturing, storage and transport.

Exosomes in Regenerative Medicine

Exosomes are nanosized vesicles released by all cell types, including stem cells. Dr Lim at the Hudson Institute, and Professor Wallace at Monash University, found that exosome treatment is highly effective in numerous fibrotic disease models (e.g. liver and lung disease). Exosomes can be derived from human placental amniotic epithelial stem cells (hAECs). Amniotic exosomes exhibit immuno-modulatory, anti-fibrotic and pro-regenerative effects.

Clinical Benefits of Amniotic Exosomes

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. 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. Plus, since exosomes are more robust, multiple routes to treatment delivery are possible (intravenous, topical, nebulised, nasal spray, inhaler).

Global Market Opportunity

Platform Technology

A number of exosome companies with strong financial backing strengthen the commercial confidence of exosomes to improve human health.

Examples of pre-clinical R&D companies

Creative Medical Technologies for exosomes derived from Amniotic Stem Cells for stroke. Background patent is licensed to the company for milestones ($2m) and royalties of 5-20% (Dec 2016)

Exosome Diagnostics raised $60 million in a Series B round first blood-based cancer diagnostic to exploit free-floating exosomes became commercially available in the US on January 2016

Codiak Biosciences, a company pursuing both diagnostic and therapeutic applications, closed a $61-million B round, taking to $92 million its total raise since 2015

Stage of Development

Our proprietary exosome treatment has been shown to be equally as therapeutic, or more so, as placental stem cells in numerous fibrotic conditions, including liver and lung preclinical disease models.

To fully commercialize the product, investment is needed to develop the platform technology to point of:

1. Phase 1 trial ready
2. Regulatory approval pathway clarified
3. Bulk, clinical grade exosome manufacture achieved

Value proposition

Exosomes are gaining momentum as a novel strategy for accessing the therapeutic effects of stem cells without the risks and difficulties of directly administering the cells to patients.

The recent investments into Codiak and others highlight the substantial investment potential of exosomes and validate the exosome approach.

There are currently an estimated US $2 billion p.a. market opportunity for Nonalcoholic Steatohepatitis; US $1 - 1.2 billion p.a. for Idiopathic Pulmonary Fibrosis treatment; and US $0.3 - 0.5 billion p.a Bronchopulmonary dysplasia.

IP position

PCT/AU2016/050468 filed June 2016 - 'A method of treatment.'

Only patent on amniotic exosomes

Significant potential for future novel indication specific IP.

Commercial Partnership

Seeking US$5.5M investment to build platform exosome therapy company to treat fibrosis and other degenerative medical conditions.

The opportunity exists to establish a vehicle structured to maximize non-diluting tax rebates and government incentives for R&D active Australian businesses.

Contact

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