

ASX Announcement

3rd December 2018

Chinese Patent for Biomarkers to Monitor Disease Progression for Stem Cell Therapy

- Chinese Patent to issue covers use of biomarkers to monitor disease progression for mesenchymal stem cell (MSC) therapy for inflammatory conditions
- Grant of patent application No. 201480060270.X will provide commercial rights in China until 2033
- Patent covers use of a broad range of allogeneic and autologous MSC therapeutics for inflammatory conditions in combination with biomarkers and is not limited to MSCs sourced from adipose tissue
- Patent will provide protection for licensing the Company's Progenza allogeneic MSC therapeutics in China

Regeneus Ltd (ASX: RGS) (Regeneus or the Company), a clinical-stage regenerative medicine company, is pleased to announce the State Intellectual Property Office of China has granted the Company a patent for the use of biomarkers to monitor disease progression in a patient having mesenchymal cell therapy for inflammatory conditions.

The granted Chinese Patent Application No. 201480060270.X, entitled "Biomarkers for cell therapy", will provide the Company with commercial rights in China until 2033.

The patent covers use of a broad range of MSC therapeutics for the treatment of inflammatory conditions in combination with the biomarkers. The therapeutics include allogeneic and autologous cells where the MSCs can be sourced from any tissue type such as adipose, bone marrow or placental tissue and includes MSCs sourced from induced pluripotent stem cells and embryonic stem cells.

MSCs have well recognised anti-inflammatory effects and are used and being developed to treat a range of chronic inflammatory conditions including graft versus host disease, Crohn's disease, cardiovascular disease and osteoarthritis.

Biomarkers associated with inflammatory disease are a useful way to measure the effects of MSC therapies and can be analysed simply in a patient's blood or other body fluids. The patent covers the biomarkers MIF (Macrophage Migration Inhibitory Factor), COMP (Cartilage oligomeric matrix protein) and CTX II (crosslinked C-telopeptides of type II collagen) in MSC therapies. MIF is recognised as a key modulator in promoting and modulating the magnitude of the inflammatory response, while COMP and CTX-II are degradation products of joint tissues, especially the cartilage extracellular matrix.

This patent will provide protection for licensing the Company's Progenza allogeneic stem cell therapy platform in China.

There is increasing interest in China for in-licensing cell therapy technology platforms like Progenza. In December 2017, the Chinese government announced new laws to accelerate the approval pathway for cell therapy products. Under the new regime, cell therapy products will need to go through 2 clinical phases: an early phase focused on safety and a confirmatory phase to demonstrate probable efficacy. These new cell products will be available for government reimbursement.

Regeneus has over 80 patents or patent applications across multiple patent families, providing the Company's product pipeline with a significant competitive advantage.

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About Regeneus Ltd

Regeneus Ltd (ASX:RGS) is a Sydney-based clinical-stage regenerative medicine company using stem cell and immuno-oncology technologies to develop a portfolio of novel cell-based therapies to address significant unmet medical needs in the human and animal health markets with a focus on osteoarthritis and other musculoskeletal disorders, oncology and dermatology.

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