

Mesenchymal Stem Cells



Regeneus Ltd (ASX:RGS) is an ASX-listed clinical stage regenerative medicine company developing a portfolio of innovative cellular therapies for unmet medical needs in the human and animal health markets

Regeneus' clinical focus is on osteoarthritis (OA), cancer, inflammatory skin conditions and wound care.

Product Pipeline and Technologies

The company's product pipeline is underpinned by proprietary stem cell and immunotherapy technologies comprising:

- allogeneic off-the-shelf adipose-derived (fat) mesenchymal stem cells (MSCs) and cell secretions for OA and other inflammatory conditions (**Progenza** for humans and **CryoShot** for animals)
- allogeneic off-the-shelf bioactive secretions from adipose-derived MSCs for inflammatory skin conditions and wound care (for humans only)
- autologous cancer immunotherapy that uses the patient's tumour cells and a bacterial adjuvant for immune recognition (**RGS4K** for humans and **Kvax** for animals)

MSCs respond to the local disease environment and secrete a diverse variety of bioactive factors including cytokines and growth factors that are responsible for reducing inflammation, promoting tissue repair and reducing scarring. Progenza technology has the benefit of using MSCs from adipose tissue which assists in scaling the manufacture of the cells. The secretions also assist with the functionality of cells post thawing. The company has demonstrated the capacity to produce millions of doses of Progenza from a single donor.

Clinical Developments

The company is conducting two Phase 1 human trials: the STEP trial using Progenza to treat OA has completed recruitment and the pre-specified review of patient safety data showed no safety or tolerability concerns. The 12 month post-treatment follow-up will be completed in Q3 FY17; the cancer vaccine trial (ACTIVATE) has commenced and enrolment is anticipated to be completed in Q3 FY17. The company is conducting stability trials for its secretions technology for topical applications and is optimizing manufacture scale-up prior to conducting further clinical studies.

Regeneus is conducting two advanced clinical trials for dogs: the US pre-pivotal trial using CryoShot to treat OA is recruiting and is anticipated to complete enrollment in Q3FY17. The CryoShot canine technology is under option to a major animal health pharma. The osteosarcoma trial has completed recruitment and waiting trial results analysis. The lymphoma trial is recruiting and should be fully enrolled by the end of FY17.

Latest News

Regeneus is well advanced in discussions for licensing its Progenza technology for manufacture, development and commercialization in Japan. Japan has become an active market for partnering of stem cell technologies and therapies following the introduction in 2014 of regulations that provide an accelerated pathway to bring new cell therapies to market.

John Martin CEO

John Martin is the CEO of Regeneus and has served on the Board since early 2009 and was appointed CEO in 2014. John is an experienced CEO and director of ASX listed and private emerging technology and high growth companies including being a former director and founding shareholder of biotech spin outs from Macquarie University, BTF (now owned by Biomerieux) and Proteome Systems. John is experienced in working collaboratively with technology entrepreneurs to help build and develop early stage technology companies into investable businesses. John is a former corporate and executive partner of the international law firm, Allens, specializing in M&A, fundraising, corporate advisory and life sciences.

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Australia in 2007
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