

ASX Announcement

Breakthrough technology for high potency stem cells opens door for next generation cell therapies

Sydney, Australia – 24 November 2015

Regeneus Ltd (ASX: RGS), a clinical-stage regenerative medicine company, today announced that it has secured exclusive rights to commercialise a breakthrough cell identification and selection technology that for the first time in the world allows high potency secreting stem cells to be identified and selected for the manufacture of next generation cell therapies.

The technology was developed by researchers at the Centre for Nanoscale BioPhotonics (CNBP) at Macquarie University and uses innovative cell labelling technologies to identify and select cells based on the molecules that they are secreting rather than their surface markers. Cells secrete various molecules such as cytokines and growth factors that drive the function and therapeutic effect of cells.

Current technology is not sensitive enough to allow analysis of secretion molecules in individual live stem cells. The CNBP technology is extremely sensitive and allows researchers for the first time to identify as well as select individual live stem cells based on their capacity to secrete high levels of therapeutically powerful cytokines.

"This new identification and selection technology opens the door to better understand and control a whole host of diseases. It holds the potential for what may be called "designer cells" where a cell line is developed that is enriched for a secretion capacity which is uniquely matched to the needs of the disease in question," said Dr Graham Vesey, co-founder and Chief Scientific Officer at Regeneus.

The technology was developed in the research group led by Professor Ewa Goldys and Dr Guozhen Liu at the Australian Research Council's Centre of Excellence for Nanoscale BioPhotonics at Macquarie University. Professor Goldys who is Deputy Director of the CNBP, is pleased with the partnership: "At the CNBP, it's not just about our scientific discovery, we're also committed to commercial and real-world translational outcomes with long-term societal value. As such, we look forward to working closely with Regeneus in the development of this exciting area of research."

The parties have entered into a collaboration and licence agreement under which Regeneus will provide funding for further collaborative development of the technology and its applications at the CNBP. Macquarie University has granted Regeneus an exclusive licence over key applications of the technology for the human and animal health markets and Regeneus will pay Macquarie a royalty on revenues generated from the commercialisation of the technology.

Regeneus sees a range of significant commercial opportunities for the CNBP technology. The near term opportunities include developing analysis kits for the research and diagnostics markets. The global cell isolation market is expected to reach US\$5.1 billion by 2019 from US\$2.5 billion in 2014, growing at a CAGR of 15.8% from 2014 to 2019.

Regeneus will also use the CNBP technology to build upon its existing Progenza allogeneic stem cell platform to develop the next generation of designer cell therapeutic products where the donor cells have been carefully selected for their particular cytokine profile that have been matched to the disease. The global regenerative medicines market is estimated to reach US\$67.5bn by 2020 growing at a CAGR of 23.2% from 2014 to 2020.

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About Regeneus:

Regeneus Ltd (ASX: RGS) is a clinical-stage regenerative medicine company developing a portfolio of 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 diseases.

The company has two product candidates in Phase I trials: Progenza is an allogeneic off-the-shelf adipose stem cell therapy to treat osteoarthritis and other musculoskeletal conditions and RGSH4K is an autologous therapeutic cancer vaccine to treat a wide range of tumour types. The company is developing a stem cell secretions based cream targeting acne and other inflammatory skin conditions. The company has two therapies targeting animal conditions: CryoShot is a clinical-stage allogeneic off-the-shelf adipose stem cell therapy for the treatment of canine and equine osteoarthritis and other musculoskeletal conditions and Kvax is an autologous therapeutic cancer vaccine in clinical trials.

About the Centre of Excellence for Nanoscale BioPhotonics:

The Australian Research Council's Centre of Excellence for Nanoscale BioPhotonics brings together leading physicists, chemists and biologists from across Australia and the world with research nodes at the University of Adelaide, Macquarie University and RMIT University. The Centre seeks to extend the boundaries of knowledge in nanoscale photonics and in the science of surfaces that will power new ways of understanding cellular processes within the human body. For more details visit www.cnbp.org.au.