

## ASX ANNOUNCEMENT

### Regeneus achieves key stem cell manufacturing milestone for clinical trial

Sydney, Australia – 7 April 2015

- **Successful manufacture of “off-the-shelf” stem cell therapy product, Progenza, for First-in-Human osteoarthritis trial**
- **Demonstrates capacity to manufacture millions of therapeutic doses from a single donor**
- **On track for trial approval in first-half of 2015**

Regeneus (ASX: RGS) announced today that it has achieved a key manufacturing milestone for its proprietary “off-the-shelf” allogeneic stem cell therapy product, Progenza.

Regeneus has completed the manufacture of Progenza for its First-in-Human trial for the treatment of osteoarthritis (OA). This is the first time that Progenza has been produced at scale for use in a human trial.

This important milestone follows the company’s announcement on 9 March 2015 of the promising pre-clinical results for Progenza showing that the stem cells were safe and prevented disease progression for OA in an animal model. That study was conducted by independent Colorado-based Pre-clinical Research Services, who specialise in pre-clinical osteoarthritis models. Regeneus is on track to receive ethics approval and commence recruitment for the trial in the first-half of 2015.

Progenza is produced from adipose (fat) tissue from a healthy donor. The mesenchymal stem cells (MSCs) from the tissue are expanded through the company’s proprietary and scalable manufacturing process. When Progenza cells are injected into the damaged joint or tissue, the MSCs have shown the ability to halt the progression of disease through the production of therapeutic factors in response to the signals of inflammation and tissue damage.

During the manufacture of the cells for the trial, the company expanded the donor adipose stem cells to a scale that demonstrates the capacity to produce from a single donor millions of therapeutic doses of Progenza (based on 5 -10 million cells per dose).

“The production of commercial quantities of stem cells from a single donor is critical to maximise dose-to-dose consistency. This scale of production will minimise clinical trial and regulatory risks while reducing the cost of the final product,” said CEO John Martin.

“One of the key advantages for manufacturing Progenza at industrial scale is that it uses stem cells sourced from adipose or fat tissue. Adipose tissue is readily available from donors in large quantities and has significantly higher stem cells per gram of tissue than other tissue sources such as bone marrow or cord tissue. Also adipose derived stem cells show greater capacity for expansion than stem cells from other tissue types. Progenza adipose derived stem cells are adult stem cells, they are not genetically modified like induced pluripotent stem cells (iPSC). A less complex cell source and scalable manufacturing process will translate to a faster, less challenging regulatory approval pathway,” said Mr Martin.

The Progenza trial product was manufactured by the company's cell production experts in a Good Manufacturing Practice environment (GMP) at Cryosite's (ASX:CTE) TGA licensed facility in Sydney. The Regeneus production team leveraged their considerable experience and expertise proven in large-scale stem cell manufacture of CryoShot, the company's clinical-stage off-the-shelf allogeneic adipose stem cell product for the treatment of canine and equine musculoskeletal conditions.

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**About Regeneus:**

Regeneus Ltd (ASX: RGS) is a clinical-stage regenerative medicine company developing a patented portfolio of cell therapies to address significant unmet medical needs in the human and veterinary health markets with a focus on musculoskeletal disease, oncology and dermatology.

The company has four therapies targeting human conditions in various stages of development including two products approaching first-in-human Phase I: Progenza is an allogeneic off-the-shelf adipose stem cell therapy to treat musculoskeletal conditions and RGSH4K is a human autologous personalized therapeutic cancer vaccine to treat a wide range of cancer types. The company has a stem cell secretions based cream targeting inflammatory skin conditions and HiQCell is a commercial autologous therapy for the treatment of musculoskeletal 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 musculoskeletal conditions and Kvax is an autologous personalized therapeutic cancer vaccine in marketing trials.