

## ASX ANNOUNCEMENT

### Regeneus receives approval for Progenza stem cell trial for osteoarthritis

Sydney, Australia – 22 April 2015

Regeneus (ASX:RGS), a clinical stage regenerative medicine company focused on the development of cell therapies, announced today that it has received ethics approval for a clinical trial of its new off-the-shelf allogeneic stem cell treatment, known as Progenza, for patients with knee osteoarthritis.

Progenza is produced from adipose (fat) tissue from a healthy donor who has been extensively screened. The mesenchymal stem cells (MSCs) from adipose tissue are expanded through the company's proprietary and scalable manufacturing process that is capable of producing millions of therapeutic doses from one donor.

When Progenza stem cells are injected into a patient's osteoarthritic joint, the MSCs have the potential to reduce pain and inflammation and slow the progression of disease.

The trial is entitled, "A Phase 1 randomised, double-blind, placebo-controlled single ascending dose study to evaluate the safety, tolerability and preliminary efficacy of intra-articular Progenza in adults with symptomatic knee osteoarthritis" (the STEP Trial). The approval clears the way for site initiation and patient recruitment into the STEP Trial.

Leading Sydney-based sports medicine specialist, Dr Donald Kuah, will be the principal investigator on the STEP Trial. Dr Kuah, a principal of Sydney Sportsmed Specialists, has extensive experience in the diagnosis and treatment of patients with osteoarthritis. He is also a pioneer in the testing and use of autologous adipose-derived stem cells and platelet rich plasma for the treatment of musculoskeletal conditions.

The STEP Trial will include 20 participants with knee osteoarthritis. Participants will receive ultrasound-guided injections of Progenza or placebo directly into their arthritic knee joint. The primary objective of the trial is to evaluate the safety and tolerability of Progenza. The secondary objectives are to investigate the effect of Progenza on knee pain and function; quality of life; knee joint structures using magnetic resonance imaging; and osteoarthritis biomarkers. Participants will be monitored for 12 months with an interim safety review at 1 month post treatment.

"I'm excited to be the principal investigator of the STEP Trial evaluating the safety and preliminary efficacy of Progenza for osteoarthritis. The clinical testing of an off-the-shelf allogeneic cell therapy like Progenza which could address the underlying cause of the disease is important for providing a new potential treatment option to patients with osteoarthritis", said Dr Kuah.

The STEP Trial was approved by an independent Human Research Ethics Committee registered with the Australian Government's National Health and Medical Research Council. The Trial will be registered on the Australian New Zealand Clinical Trials Registry (ANZCTR) and notified to the Therapeutic Goods Administration through the Clinical Trials Notification Scheme.

Trial recruitment will commence as scheduled in the first-half of 2015.

**About Progenza:**

Progenza is an off-the shelf allogeneic stem cell product for the treatment of osteoarthritis. The product is produced from mesenchymal stem cells (MSCs) from adipose (fat) tissue from a healthy donor who has been extensively screened. Progenza includes secretions from donor MSCs that improves viability and functionality of the cells after freezing.

Adipose tissue is readily available from donors in large quantities and has significantly higher MSCs per gram of tissue than other tissue sources such as bone marrow or cord tissue. Also adipose-derived MSCs show greater capacity for expansion than MSCs from other tissue types that helps to increase the number of therapeutic doses from a single donor. The MSCs from adipose tissue are expanded through the company's proprietary and scalable manufacturing process. The company has demonstrated the capacity to produce from a single donor, millions of therapeutic doses of Progenza.

When Progenza cells are injected into the damaged joint or tissue, the MSCs have the potential to reduce pain and inflammation and slow the progression of disease.

**Further information:**

John Martin  
Chief Executive Officer  
T: 0408544395  
E: john.martin@regeneus.com.au

Sandra McIntosh  
Company Secretary and Investor Enquiries  
T: +61 2 9499 8010  
E: investors@regeneus.com.au or go to [www.regeneus.com.au](http://www.regeneus.com.au)

**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 trials: Progenza is an allogeneic off-the-shelf adipose stem cell therapy to treat musculoskeletal conditions and RGS4K 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.