

## ASX ANNOUNCEMENT

### First patient treated in Progenza stem cell trial for knee osteoarthritis

Sydney, Australia – 10 August 2015

Regeneus (ASX: RGS), a clinical-stage regenerative medicine company, today announced that the first patient has been enrolled and treated in the **STEP** (Safety, Tolerability and Efficacy of Progenza) trial, the first clinical trial of Progenza, the company's allogeneic stem cell product for the treatment of knee osteoarthritis.

A review of the sentinel patient's safety data by the study safety oversight committee identified no safety concerns. Enrolment is now open to the remainder of the first cohort of 10 patients. A second and final cohort of 10 patients will receive a higher dose of cells.

The dosing of the first patient in the **STEP** trial achieves another milestone in the clinical development of the company's allogeneic stem cell therapy.

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".

Leading Sydney-based sports medicine specialist, Dr Donald Kuah, is the Principal Investigator on the trial. Dr Kuah, a partner of Sydney Sportsmed Specialists, has extensive experience in the diagnosis and treatment of patients with osteoarthritis.

The trial will include 20 participants with knee osteoarthritis treated at two different doses of cells. Participants will receive ultrasound-guided injections of Progenza or placebo directly into their arthritic knee joint. One in five patients will receive a placebo injection. 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.

#### **About Progenza:**

Progenza is an off-the-shelf allogeneic stem cell product with the first targeted treatment being for knee 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. Adipose-derived MSCs also have the added advantage of showing greater capacity for expansion than MSCs from other tissue types. The MSCs are expanded through the company's proprietary and

scalable manufacturing process. The company has demonstrated the capacity to produce millions of therapeutic doses of Progenza from a single donor.

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.

**About Osteoarthritis:**

Osteoarthritis continues to be an unmet medical need and is a significant global concern due to ageing populations. Stem cell products, such as Progenza, may address the treatment gap for patients who have persistent joint pain, and for whom total knee replacement is likely.

**Further information:**

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**About Regeneus:**

Regeneus Ltd (ASX: RGS) is a clinical-stage regenerative medicine company developing a 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 in Phase I trials: 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 acne and other inflammatory skin conditions and HiQCell is an 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 clinical trials.