

ASX Announcement

Enrolment completed and positive safety review in Progenza stem cell trial for osteoarthritis

Sydney, Australia – 16 May 2016

Regeneus (ASX: RGS), a clinical-stage regenerative medicine company, today announced completion of enrolment of all 20 patients in the STEP trial. Further, a review of the cumulative study safety data by the study safety oversight committee identified no safety concerns.

The STEP trial (Safety, Tolerability and Efficacy of Progenza) is the first clinical trial of Progenza, the company's allogeneic off-the-shelf stem cell product for the treatment of knee osteoarthritis.

The completion of enrolment Cohort 2 ahead of schedule is a positive milestone for the clinical development of the company's allogeneic stem cell therapy. The lack of safety concerns identified from the pre-specified review of the cumulative safety data from all 20 patients is also encouraging. The review included a minimum of 1-month safety data for all patients, and substantially more data for earlier enrolled Cohort 1 patients.

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 principal of Sydney Sportsmed Specialists, has extensive experience in the diagnosis and treatment of patients with osteoarthritis.

The study will complete once the last patient completes 12 months of post treatment follow up, concluding with a second MRI. All 20 participants have knee osteoarthritis and received ultrasound-guided injections of Progenza or placebo directly into their arthritic knee joint. One in five patients received 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.

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-based therapies to address significant unmet medical needs in the human and animal health markets with a focus on osteoarthritis and other musculoskeletal disorders and oncology.

The company has two product candidates in Phase 1 trial: Progenza is an allogeneic off-the-shelf adipose stem cell therapy to treat osteoarthritis and other musculoskeletal conditions and RGS4K 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.