

PRESS RELEASE

Regeneus reports positive preclinical results for off-the-shelf cell therapy treatment for osteoarthritis

Sydney, Australia – 9 March 2015

- **Preclinical results confirm that Progenza is safe and prevents disease progression in a model of osteoarthritis**
- **Progenza is on track to move into the clinic for a “First-in-Human” study**

Regenerative medicine company, Regeneus (ASX: RGS) announced today that it has successfully completed a preclinical study to support its first-in-human safety study of Progenza, its allogeneic, off-the-shelf stem cell product for osteoarthritis (OA). Regeneus will proceed with its ethics application for the commencement of a clinical trial to assess safety and preliminary efficacy of Progenza in patients with knee OA.

“This is an important milestone in taking Progenza through the regulatory approval process” said Janet Wilson, Clinical Research Director at Regeneus. The Good Laboratory Practice (GLP)-compliant preclinical study was conducted at a US-based facility with expertise in conducting preclinical studies that replicate human OA. The results showed no Progenza-related safety or toxicity issues, even at doses well in excess of the intended human dose. Further, Progenza-treated knees showed no deterioration from the time of injection, in contrast to the vehicle control group, which continued to deteriorate over the 7-week study. These study results support the role of Progenza in preventing disease progression.

“As we have qualified the trial product in preclinical work, our next step is to seek ethics approval for the first-in-human trial. The planned trial is a single centre study and will include patients with symptomatic knee OA. Progenza will be injected once into the knee. Safety will be monitored closely and assessments for preliminary efficacy, such as MRIs pre and post treatment, are also included” said Janet Wilson.

The source material for Progenza is adipose tissue (fat) from a healthy donor. The stem cells from the tissue are expanded through a proprietary manufacturing process that allows large numbers of therapeutic doses to be produced from a single donor. The production of donor off-the-shelf stem cell product is to be contrasted with autologous stem cell therapy where a patient's own stem cells are used as the therapeutic product. Stem cells, such as Progenza, work by homing to the site of injury and damage, exerting action through the production and release of various growth factors and anti-inflammatory proteins to stop cell death and promote healing and normal growth.

OA 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 OA pain, and for whom total knee replacement is likely.

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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 RGS4K is a human autologous personalized therapeutic cancer vaccine to treat a wide range of cancer types. The company has developed a stem cell 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-phase allogeneic off-the-shelf adipose stem cell therapy for the treatment of canine and equine musculoskeletal conditions and Kvax is a commercial autologous personalized therapeutic cancer vaccine in marketing trials.