

ASX Announcement

Progenza granted Advanced Therapy Medicinal Product designation by European Medicines Agency

Sydney, Australia – 14 February 2018

Regeneus (ASX:RGS), a clinical-stage regenerative medicine company, today announced that Progenza has been granted an Advanced Therapy Medicinal Product (ATMP) classification by the Committee for Advanced Therapies (CAT) of the European Medicines Agency (EMA), following consultation with the European Commission. Progenza is the company's allogeneic stem cell technology platform for the treatment of osteoarthritis and other inflammatory conditions for human applications.

"The granting of the ATMP classification for Progenza, is a step towards bringing Progenza to Europe as a novel cell therapy treatment for osteoarthritis. It's important to have regulatory clarity as we invest in the development of Progenza," said John Martin, CEO of Regeneus.

ATMP classified products are novel regenerative therapies that combine aspects of medicine, cell biology, science and engineering and are presented as having properties with a view to regenerating, repairing or replacing a human tissue. ATMPs comprise cell and gene therapies and tissue-engineered products. Their classification is defined in Article 2 (4) of Regulation (EC) No 1394/2007, which establishes the legal and regulatory framework for ATMPs in the European Union.

According to the World Health Organization, an estimated 10%-15% of all adults over 60 have some degree of osteoarthritis, with prevalence higher in women than men. Given that there are few preventative and therapeutic options for osteoarthritis and that the European population is ageing, the burden of osteoarthritis is predicted to rise.

More about Progenza stem cell technology

Progenza is an allogeneic off-the-shelf stem cell technology platform developed for the treatment of knee osteoarthritis and other inflammatory conditions. Results of a Phase 1 safety trial of Progenza in knee osteoarthritis met primary endpoints of safety and tolerability. Secondary endpoints showed a significant, rapid and sustained reduction in knee pain, and significant improvement in cartilage volume compared to placebo, with positive signs of disease modification.

Progenza cells work by secreting cytokines, growth factors and exosomes that act in concert to reduce inflammation and pain and encourage accelerated healing and repair of the damaged or diseased tissue.

Progenza is produced from expanded mesenchymal stem cells (MSCs) extracted from adipose (fat) tissue from a healthy donor who has been extensively screened. Unlike other stem cell products, Progenza includes secretions from MSCs that improve viability and functionality of the cells during the freezing and thawing process. Regeneus has shown that the combination of cells and secretions has a more powerful therapeutic effect than cells alone.

There are significant advantages in using adipose-derived MSCs to manufacture Progenza. 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 which helps avoid the need to pool donor material and seek multiple donors. The MSCs used in Progenza have not been reprogrammed as required for induced pluripotent stem cells thereby reducing manufacturing and clinical development risks.

Regeneus has granted Asahi Glass (AGC) of Japan exclusive rights to manufacture Progenza for all clinical applications in Japan. AGC is a leading Japanese biopharmaceutical manufacturer. Regeneus Japan (a 50/50 JV with AGC) is responsible for licensing the clinical development and marketing rights of Progenza in Japan.

Regeneus has been granted a patent in Australia and Japan covering the manufacture and use of Progenza for the treatment of osteoarthritis and other inflammatory conditions. The patent is also being pursued in Europe and USA.

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About Regeneus:

Regeneus Ltd (ASX: RGS) is a Sydney-based clinical-stage regenerative medicine company using stem cell and immuno-oncology technologies to develop a portfolio of innovative 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, oncology and dermatology.