

ASX Announcement

Regeneus announces Japanese Patent Office decision to grant key patent for Progenza stem cell technology

Sydney, Australia – 24 May 2017

Regeneus (ASX: RGS), a clinical-stage regenerative medicine company, today announced that the Japanese Patent Office has issued a decision to grant a key patent covering the composition, manufacture and use of Progenza stem cell technology. Progenza is the company's allogeneic off-the-shelf stem cell technology platform for the treatment of osteoarthritis and other inflammatory conditions for human and animal applications.

Japanese Patent Application No. 2014-531048 entitled "Therapeutics using cells and cell secretions" will provide commercial rights in Japan through to 2032. Corresponding patents have been granted in Australia and New Zealand and are being pursued for grant in other key territories including the USA and Europe.

Progenza rights for all clinical applications in Japan have been licensed exclusively to Regeneus Japan Inc, a company jointly owned by Regeneus and AGC of Japan. Progenza rights for manufacture in Japan have been licensed exclusively to AGC. Regeneus Japan is in advanced discussions with potential licensees of Progenza rights for disease specific indications in Japan.

"The timing for the issue of this patent in Japan couldn't be better. It comes on the back of having announced positive data from our Phase 1 STEP trial of Progenza for knee osteoarthritis. The combination of positive clinical data, an issued patent and our strategic collaboration with AGC, will put us in a strong position to convert our clinical partnering discussions into good commercial outcomes", said John Martin Regeneus CEO. "Japan continues to be the most attractive market for clinical licensing opportunities for Progenza technology underpinned by a world leading regulatory framework for encouraging the development and early patient access to new regenerative medicine products and an engaged pharmaceutical and biotechnology industry," said Mr Martin.

Regeneus has 56 patents or patent applications across 14 patent families which provides a substantial competitive advantage for the company's product pipeline.

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. 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 improves viability and functionality of the cells during the freezing and thawing process. Regeneus has shown that a 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 reduces 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.

ENDS

Contact for further information:

Investors:

Sandra McIntosh
Investor Relations
Regeneus Ltd
T: +61 2 9499 8010
E: investors@regeneus.com.au or go to www.regeneus.com.au

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.