

## ASX Announcement

### Regeneus and AGC Asahi Glass to collaborate on Progenza regenerative medicine therapy in Japan

Sydney, Australia – 29 December 2016

#### Key Points

- Regeneus collaborates with AGC Asahi Glass (AGC), a world-leading manufacturer of glass, chemicals, high-tech materials and biopharmaceuticals, for exclusive manufacture of Progenza stem cell technology for Japanese market
- Regeneus to receive US\$16.5m with US\$5.5m upfront and US\$11m in specified milestone payments
- Regeneus and AGC establish 50/50 joint venture for exclusive clinical development and commercialisation of Progenza for osteoarthritis and all inflammatory conditions for Japanese market
- AGC to expand its leading biopharma manufacturing business into regenerative medicine products

Regeneus Ltd (ASX: RGS), a clinical-stage regenerative medicine company, today announced that it has entered into a strategic collaboration and licensing agreement with AGC Asahi Glass (AGC) (TYO:5201), a world-leading manufacturer of glass, chemicals, high-tech materials and biopharmaceuticals, for the manufacture, clinical development and commercialization of Progenza, a patented off-the-shelf stem cell technology platform, for the Japanese market.

#### Overview of collaboration

Under the terms of the agreement, Regeneus grants AGC exclusive rights to manufacture Progenza in Japan and a 50 percent interest in Regeneus Japan, which has the exclusive rights for the clinical development and commercialisation of Progenza in Japan for osteoarthritis and all therapeutic applications.

Regeneus will receive US\$16.5 million from AGC, with US\$5.5million as an upfront payment and the remaining \$11m in specific development and approval milestone payments. Regeneus will also be entitled, through its 50% interest in the joint venture, to its share of upfront licence fees, milestone payments and royalties from sub licensing the development and commercialization of Progenza for osteoarthritis and all other clinical indications in Japan.

AGC will be responsible for funding the manufacture of Progenza for the proposed Phase 2 trial for osteoarthritis in Japan under specific conditions.

#### Osteoarthritis represents a major problem in Japan and globally

Osteoarthritis represents a major health challenge in Japan as it has a rapidly ageing population and access to and acceptance of joint replacement surgery for severe knee osteoarthritis is limited. Worldwide, osteoarthritis is estimated to be the fourth leading cause of disability. There is no cure for the debilitating disease and non-steroidal anti-inflammatory medication is the most common treatment for the pain symptoms although they can have adverse affects with over use. In Japan, knee injections of hyaluronic acid are a common treatment to manage pain associated with osteoarthritis, but it has limited effect.

Over the last 12 months, Progenza has been evaluated as a treatment for knee osteoarthritis in a Phase 1 trial conducted in Sydney. A safety review of both treatment cohorts found there were no safety or tolerability

concerns with Progenza. All patients are being followed for 12 months and the study results will be made available in the second quarter of 2017.

The joint venture will take over the current partnering discussions for the clinical development and commercialisation of Progenza for knee osteoarthritis and other inflammatory disorders in Japan.

The parties will collaborate to manufacture Progenza for the proposed Phase 2 trial in Japan and regulatory engagement. AGC will be responsible for the costs associated with the manufacture of the trial product under certain conditions.

### **Japan is a leading market for regenerative medicine**

Japan represents the second largest national healthcare market in the world. It has a rapidly ageing population that poses unique challenges for the healthcare system over the medium term. In order to address these challenges, the Abe Administration has made the development of the cell and tissue regeneration industry as one of the pillars of Japan's growth strategy.

In November 2014, Japan introduced new laws to focus on and accelerate the development and early patient access to innovative new regenerative medicines where there is substantial unmet medical need that are demonstrated to be safe and provide promising signs of effectiveness. This allows for the conditional approval of new regenerative medicine treatments without having to wait for the completion of long and expensive Phase 3 trials. This government strategy has resulted in a significant increase in R&D and corporate activity in the regenerative medicine sector over the last 2 years. The market in Japan for regenerative medicines is projected to grow to US\$12.7billion by 2030 according to the Japanese government.

### **Alignment with AGC's strategy to grow life sciences business**

John Martin, CEO of Regeneus, said, "We are excited to announce our collaboration with AGC. AGC is a world-class technology driven multinational company headquartered in Tokyo with a clear vision and strategic priority to grow its life science business. This makes AGC an ideal fit for us to manufacture and jointly develop and commercialise Progenza stem cell technology in Japan through clinical marketing partners. As a leading manufacturer of biopharmaceutical products in Japan with recent acquisitions of manufacturing capability in Europe and the USA, AGC is well placed to expand into the fast growing market for manufacturing regenerative medicine products. We look forward to having Progenza manufactured by AGC in Japan and the value AGC will bring to accelerate clinical development of Progenza through its extensive relationships with Japanese pharmaceutical companies, regulators and local market knowledge".

### **About Progenza stem cell technology**

Progenza is an allogeneic off-the-shelf stem cell technology developed for the treatment of knee osteoarthritis and other inflammatory conditions. Progenza cells work by secreting cytokines and growth factors 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 such as bone marrow or blood. 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.

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

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**Contact for further information:****Investors:**

Sandra McIntosh  
Investor Relations  
Regeneus Ltd  
T: +61 2 9499 8010  
E: [investors@regeneus.com.au](mailto:investors@regeneus.com.au) or go to [www.regeneus.com.au](http://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.

**About AGC Group:**

AGC Asahi Glass (or also called AGC, Registered Company name: Asahi Glass Co., Ltd., Headquarters: Tokyo, President & CEO: Takuya Shimamura) is the parent company of the AGC Group, a world-leading glass solution provider and supplier of flat, automotive and display glass, chemicals, biopharmaceuticals, ceramics and other high-tech materials and components. Based on more than a century of technical innovation, the AGC Group has developed a wide range of cutting-edge products. The AGC Group employs some 50,000 people worldwide and generates annual sales of approximately 1.3 trillion Japanese yen through businesses in about 30 countries. For more information, please visit: [www.agc-group.com](http://www.agc-group.com).