

PRESS RELEASE

Regeneus receives ethics approval for collecting stem cells from human donors for first-in-man safety trial of its off-the-shelf treatment for osteoarthritis

Sydney, Australia – 8 April 2014

Regenerative medicine company, Regeneus (ASX: RGS) announced today that it has received ethics approval to collect stem cells from human donors for use in production of its new allogeneic off-the-shelf stem cell product for osteoarthritis (OA). This approval allows Regeneus to begin manufacturing the cells for its first-in-man clinical trial to assess initial safety and preliminary efficacy in human volunteers with knee OA.

"This is an important first step in taking our human allogeneic product for osteoarthritis through the regulatory approval process" says Dr Richard Lillischkis, Clinical Development Director at Regeneus. "We are collecting adipose tissue (fat) from human donors and are extracting and expanding the stem cells to produce large numbers of vials of frozen stem cells for use in clinical trials".

Access to an off-the-shelf product will mean stem cell therapy is less invasive for patients than autologous treatments and provide a convenient treatment option for specialists. The treating doctor will simply remove a vial of cells from the freezer, thaw the cells and inject them in to the patient's joints. The new product will need to pass through the usual safety and efficacy trials to achieve market access.

The company has targeted the Japanese market for its allogeneic stem cell product to take advantage of the new laws passed in November 2013 that provide an accelerated approval process for allogeneic human cell therapies without the need for expensive phase III clinical trials.

Regeneus is a pioneer in the development and use of adipose-derived stem cell products to provide an effective treatment for OA in humans and animals. The company markets an autologous product, HiQCell, that has been used to treat over 1,000 human arthritic joints in clinical trials and commercial settings. The company has also developed and manufactures a clinical stage allogeneic off-the-shelf product, CryoShot, that has been used in trials to treat 100s of cases of canine and equine OA. Through the development and testing of CryoShot, the company has developed considerable expertise in product design, tissue sourcing, manufacture, handling and delivery in-clinic of an off-the-shelf stem cell product.

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About Regeneus:

Regeneus Ltd (ASX: RGS) is a Sydney-based ASX listed regenerative medicine company that develops and commercialises novel autologous (your cells) and allogeneic (donor cells) cell therapies for humans and animals. The company has a marketed autologous product to treat human osteoarthritis, HiQCell, which has been used to treat over 1000 arthritic joints. The company plans to commence a clinical trial of allogeneic adipose stem cells to treat human osteoarthritis in H12015.

Regeneus' lead cell therapy for the animal health market is CryoShot, a clinical stage allogeneic adipose stem cell product for the treatment of canine and equine osteoarthritis. CryoShot is scheduled for a US registration trial in H12015. The company has a clinical stage autologous immunotherapy for canine cancer which will commence marketing trials in US and Australia in H2 2014. The company also holds an option over the rights for human applications of the immunotherapy.