



# Regeneus Limited

Apr 8<sup>th</sup> 2015

## Regeneus hits key stem cell manufacturing milestone

Regeneus (ASX: RGS) has achieved a key milestone with the manufacture of its "off-the-shelf" stem cell therapy product Progenza for its First-in-Human trial for the treatment of osteoarthritis.

The company is on track to receive ethics approval and commence recruitment for the trial in the first-half of 2015.

Adding interest, the company highlighted the benefit of using adipose or fat tissue over other tissue types by demonstrating the capacity to produce millions of therapeutic doses of Progenza from a single donor.

"The production of commercial quantities of stem cells from a single donor is critical to maximise dose-to-dose consistency," chief executive officer John Martin said.

"This scale of production will minimise clinical trial and regulatory risks while reducing the cost of the final product.

"One of the key advantages for manufacturing Progenza at industrial scale is that it uses stem cells sourced from adipose or fat tissue.

"Adipose tissue is readily available from donors in large quantities and has significantly higher stem cells per gram of tissue than other tissue sources such as bone marrow or cord tissue.

"Also adipose derived stem cells show greater capacity for expansion than stem cells from other tissue types.

"Progenza adipose derived stem cells are adult stem cells, they are not genetically modified like induced pluripotent stem cells (iPSC).

"A less complex cell source and scalable manufacturing process will translate to a faster, less challenging regulatory approval pathway."

The Progenza trial product was manufactured by the company's cell production experts in a Good Manufacturing Practice environment (GMP) at Cryosite's (ASX:CTE) TGA licensed facility in Sydney.

Regeneus' production team leveraged their considerable experience and expertise proven in large-scale stem cell manufacture of CryoShot, the company's clinical-stage off-the-shelf allogeneic adipose stem cell product for the treatment of canine and equine musculoskeletal conditions.

### Pre-Clinical Study

In March, the company successfully completed a pre-clinical study at a US-based facility with expertise in conducting preclinical studies that replicate human OA.

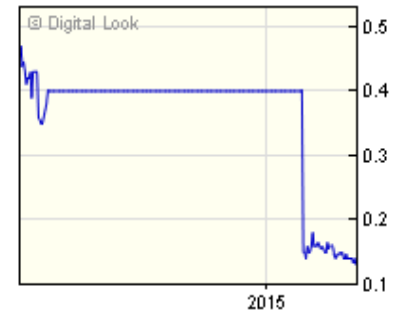
The results showed no Progenza-related safety or toxicity issues, even at doses well in excess of the intended human dose.

Further, Progenza-treated knees showed no deterioration from the time of injection, in contrast to the vehicle control

**Price:** A\$0.13

**Market Cap:** A\$20.906M

### 1 Year Share Price Graph



### Share Information

**Code:** RGS

**Listing:** ASX

**Sector:** Medical Supplies

**Website:** www.regeneus.com.au

### Company Synopsis:

*Regeneus (ASX:RGS) is a Sydney based regenerative medicine company that is focused on using the regenerative capacities of adipose-derived cells to develop innovative cell therapies for humans and animals.*

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group, which continued to deteriorate over the 7-week study.

These study results support the role of Progenza in preventing disease progression.

## Analysis

Regeneus continues to progress towards its First-in-Human trial for the treatment of osteoarthritis using its "off-the-shelf" stem cell therapy product Progenza.

This is on track to commence recruitment for the trial in the first-half of 2015.

Already, the capacity to produce millions of therapeutic doses of Progenza from a single donor has demonstrated the benefit of using adipose tissue over other tissue types.

This includes the ready availability of adipose tissue, its higher stem cell count per gram of tissue and greater capacity for expansion.

In addition, the adipose derived stem cells are adult stem cells and not genetically modified like induced pluripotent stem cells.

Taken together, these translate to a faster, less challenging regulatory approval pathway.

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