

ASX Announcement

AFL approves use of Regeneus' stem cell therapy, HiQCell® for injured players

Sydney, Australia – 27 August 2014

Regeneus Ltd (ASX: RGS) announced today that the Australian Football League (AFL) has granted case-by-case approval for the use of its innovative stem cell therapy, HiQCell® as a treatment option for injured AFL players, typically including impact related osteoarthritis and tendonitis.

Regeneus' Commercial Development Director for Human Health, Steve Barbera, said, "It's pleasing that HiQCell has been approved under the new AFL Prohibited Treatments List released in March 2014. HiQCell also received clearance as an approved therapy from the Australian Sports Anti-Doping Authority (ASADA) for use with athletes who participate in sporting competitions subject to the WADA Anti-Doping Code, including the AFL. This recent decision by the AFL demonstrates a further level of compliance, specifically for players within that sporting code".

HiQCell is the only stem cell treatment for osteoarthritis that has undergone the highest level of clinical scrutiny – a double blind placebo-controlled safety trial. The clinical trial demonstrated that HiQCell is safe and treatment reduces pain and halts cartilage degradation in arthritic joints. In addition to the placebo-controlled trial, the ongoing effect of HiQCell is being tracked in over 380 patients in an independent ethics approved registry. A recent registry update demonstrates that patients are maintaining significant improvements at 2 years post-treatment.

Regeneus is encouraged that elite sports patients are able to accelerate their return from hard to treat injuries and continue their playing careers after receiving the innovative HiQCell therapy. HiQCell has also been used to treat a number of elite and high-profile athletes across several sporting codes, including the NRL, as announced on 7 May 2014.

Dr Phil Bloom, a Melbourne based Specialist Sports and Exercise Physician and HiQCell treating medical practitioner, said, "permission from the AFL for HiQCell treatment is a positive progression as it allows for an additional option for players with conditions that are unresponsive to existing treatments".

The HiQCell treatment involves harvesting a small amount of a patient's own stem cells from their adipose (fat) tissue and after separating and concentrating the regenerative cells these are re-injected in osteoarthritic-affected joints such as knees, hips and ankles. The HiQCell treatment, which aims to reduce inflammation and repair damaged tissue is carried out under the supervision of the treating medical practitioner.

The AFL's approval was reported in Fairfax media outlets including the Melbourne Age and Sydney Morning Herald on 23 August 2014 (<http://www.theage.com.au/afl/afl-news/afl-approves-stemcell-therapy-treatment-20140823-107ivw.html>)

For more information on HiQCell please call 1300 573 669 or go to www.hiqcell.com.au

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About Regeneus:

Regeneus Ltd (ASX: RGS) is a Sydney-based ASX listed regenerative medicine company that develops and commercialises stem cell and other biological therapies for the human and veterinary health markets with a focus on musculoskeletal and oncology conditions. The company has a marketed autologous (patient's cells) product using adipose (fat) derived stem cells to treat human osteoarthritis (OA), HiQCell, which has been used to treat over 1000 arthritic joints. The company plans to commence a clinical trial of allogeneic (donor cells) adipose stem cells to treat human OA in Q2 2015.

Regeneus' lead product for the veterinary health market is CryoShot, a clinical stage allogeneic adipose stem cell product for the treatment of canine and equine OA. CryoShot canine is scheduled for a US registration trial in Q4 2015. Regeneus has a clinical stage autologous therapeutic cancer vaccine, Kvax, which will commence marketing trials in the US and Australia in Q4 2014. The company has also acquired in July 2014 the exclusive rights to commercialise the vaccine technology for human applications and plans to commence a first-in-man study in Q2 2015.

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