ASX Announcement

Response to 7.30 media commentary

Sydney, Australia – 9 October 2014

Regenerative medicine company Regeneus Ltd (ASX: RGS) wishes to officially respond to the ABC 7.30's *Sell Therapy* story, which aired on 6th October 2014.

Regeneus was approached by an ABC reporter asking for an interview about the science behind Regeneus' proprietary HiQCell® procedure, an autologous cell therapy for the treatment of osteoarthritis. The reporter had previously interviewed a patient who had been treated by her orthopaedic surgeon with the HiQCell procedure and had not had a satisfactory reduction in her joint pain. The patient had subsequently seen a new orthopaedic surgeon who was critical of HiQCell. During the interview the journalist asked questions well outside the stated scope of the interview, directing a series of claims and questions to Dr Herbert (Regeneus' Co-founder and Non-executive director), that he was not reasonably able to respond to in the circumstances.

A summary of the key claims of the story and the company's response is set out as follows:

1. **The story suggested that the Regeneus ASX release dated 27th August 2014 was misleading in regards to the clinical results referred to in the release.**

   Regeneus wishes to state that at the time of the interview, it was not aware of any complaint being made to the ASX, and was only made aware of a complaint being lodged following the interview, when it made an enquiry to the ASX. The ABC reporter did not inform Regeneus or Dr Herbert of the complaint, or its nature, prior to the interview. The reporter stated that the purpose of the interview was to ask questions about the science behind HiQCell.

   To date Regeneus has not seen the complaint letter referred to in the 7.30 story.

   The 7.30 report said that the complaint letter stated the announcement "… is misleading because the control (placebo) group in that trial also achieved the same reduction in pain and slowing of cartilage degeneration." A reasonable person, ".... would draw the conclusion that the company's product had been shown to be clinically efficacious when rigorously tested." ... there are no data we are aware of that support that conclusion."

   Regeneus does not consider that the ASX announcement was misleading.

   The results of Regeneus' double blind clinical study (OSCARS study) did demonstrate that the HiQCell treatment is safe, reduces pain and halts cartilage degradation. There were statistically significant differences between the HiQCell group and placebo group in key biomarkers related to inflammation and cartilage degradation.

   The placebo group in the OSCARS study also demonstrated a reduction in pain, which is common in osteoarthritis trials. Regeneus has previously published information on the OSCARS study in which it disclosed that both the treatment group and the placebo group showed a reduction in pain scores (see page 25 of Regeneus' IPO Prospectus dated 5th August 2013 and ASX announcement dated 8th October 2013 relating to biomarkers in the OSCARS study).

   The biomarker announcement dated 8th October 2013 described how in the OSCARS study, treatment with HiQCell stabilised levels of CTX-II in urine, an important cartilage-specific breakdown molecule that increases in patients with osteoarthritis as the disease progresses. Patients that received the placebo showed a significant increase in CTX-II over the course of the study whereas patients that received the HiQCell treatment showed no increase.

The purpose of the recent ASX announcement was not to repeat the OSCARS findings in detail. Rather it was intended to disclose that the AFL had approved the use of HiQCell on a case-by-case basis as not being in breach of their new Prohibited Treatments List. Regeneus chose not to include a further description of the placebo pain results, as the placebo effect is a complex issue that is not easily communicated with a few sentences.

Regeneus is committed to publishing the results of its clinical trials. A final manuscript that fully describes the OSCARS study has been prepared and Regeneus expects to submit it to the peer review journal *Osteoarthritis and Cartilage*.

2. **The story suggested that the Regeneus ASX release dated 27th August 2014 was misleading in regards to approval from the AFL of HiQCell as a treatment option for AFL players.**

Regeneus does not consider that its ASX announcement was misleading.

On 7th March 2014, the AFL introduced a Prohibited Treatments List as an additional level of player compliance to its pre-existing Anti-Doping Code and the World Anti-Doping Agency Code.

Regeneus subsequently became aware of this List from an AFL club doctor who is also a HiQCell medical practitioner, and who requested that Regeneus seek clarification from the AFL on HiQCell's compliance to the List.

On 16th July 2014, Regeneus, in conjunction with the AFL club doctor, provided the AFL with a comprehensive submission that referenced regulatory, legal, scientific and medical considerations of cell therapy in general and HiQCell specifically. The submission sought confirmation that the AFL considered HiQCell to not be a Prohibited Treatment and therefore approved for possible use with players. Relevantly, the submission included confirmation that the Australian Sports Anti-Doping Authority (ASADA) had stated in writing that it did not consider that the use of HiQCell was a Prohibited Treatment under the World Anti-Doping Code or it's Prohibited List.

On 19th August 2014, the AFL club doctor who jointly made the submission with Regeneus to the AFL confirmed in writing to Regeneus that he had received verbal approval by the AFL Medical Director for treatment on a case-by-case basis for AFL players. Since that time, a number of AFL players have been treated by the club doctor following request to and approval from the AFL Chief Medical Officer, thereby indicating that the approval process is in effect on the required case-by-case basis.

On 24th August, a news story carried in the Age newspaper and other Fairfax publications reported that the AFL had confirmed that HiQCell was approved for treatment on a case-by-case basis for AFL players. The company did not initiate this story.

On 25th August, Regeneus emailed the AFL about the newspaper coverage informing them that in light of the media commentary and the company's ASX disclosure obligations, it was proposing to put out its own media release. A copy of the proposed release was provided to the AFL at that time.

The AFL did not respond to the email or a follow up phone call from the company, or with any other communication to Regeneus and the company issued its release on 27th August.

3. **In the story, a female patient stated that she had felt pain and discomfort following the procedure and had subsequently had joint replacement surgery.**

It is difficult for us to comment on the treatment outcome for a particular patient. Regeneus is the developer and provider of HiQCell technology and associated services to medical specialists, and does not directly diagnose, consent, or medically supervise any treatment to be administered to the patient.

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Due to the confidential nature of the physician and patient relationship, Regeneus has minimal knowledge of a patient's prior condition and whether they were properly diagnosed as an appropriate candidate for the HiQCell procedure or if they elected to have HiQCell as a way of potentially delaying or avoiding joint replacement surgery, knowing the risks. Further, some patients have HiQCell as an adjunct to arthroscopy surgery, which can have a significant effect on their overall medical outcome, including pain and discomfort. Regeneus informed the reporter in writing of this potential outcome for such patients, however this information was not disclosed in the final editing of the story by either the reporter or the patient's new orthopaedic surgeon who performed the joint replacement surgery.

It is normal medical practice for a physician to provide comprehensive information on how a procedure works, the risks and potential benefits involved, prior to the patient consenting to the procedure. Regeneus informs and updates specialists who use HiQCell of the clinical data supporting the procedure. Further, the company continues to invest in the collection of HiQCell clinical data.

Clinical results to date show that the large majority of patients have success with the HiQCell therapy. At no time during the interview did the reporter refer to or report on any of the many positive patient experiences with HiQCell.

4. Bartram and Hodkinson not treated with HiQCell

While it was not expressly mentioned in the story, the way it was compiled may have left the viewer under the impression that HiQCell was the reason for former AFL player Clint Bartram's treatment failure. Regeneus notes that Mr Bartram was not treated using HiQCell.

The story also reports that current NRL player Trent Hodkinson was treated with a stem cell injection by Regeneus. This is incorrect, as Mr Hodkinson was not treated with HiQCell or by any other Regeneus procedure.

5. The story inferred that Regeneus had taken shortcuts in the evaluation of safety and efficacy.

HiQCell has been used to treat over 550 patients in Australia since 2011. This includes patients in a world-first double blind clinical study (OSCARS), and commercial patients, many of whom are followed in an ethics approved HiQCell Joint Registry. This dataset shows that the treatment is effective in reducing pain in 73% of follow-up patients at one year and 82% of follow up patients at 2 years post-treatment, as well as reducing reliance on medication and improving quality of life. The success rate of HiQCell is published on the HiQCell website (http://hiqcell.com.au/about-hiqcell/patient-results/) and communicated to patients by HiQCell licensed medical specialists.

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About Regeneus:

Regeneus Ltd (ASX: RGS) is a Sydney-based ASX listed regenerative medicine company that develops and commercialises cell 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 1,200 joints. The company plans to commence a clinical trial of allogeneic (donor cells) adipose stem cells to treat human OA in Q1 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 has commenced marketing trials in the USA.. 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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