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ASX Announcement

Stem Cells have positive results on early orthopaedic developmental disease in Yearling Thoroughbreds

Sydney, Australia – 5 November 2015

Regeneus (RGX: ASX), a clinical-stage regenerative medicine company, announced today interim trial results showing that its allogeneic "off-the-shelf" stem cell therapy, CryoShot, has positive results on early orthopaedic developmental disease in Yearling Thoroughbreds and compares favourably against the use of conventional therapies like corticosteroids. The preliminary results were presented by leading equine surgeon and principal investigator, Chris O'Sullivan from Randwick Equine Centre (REC), at the recent American College of Veterinary Surgeons (ACVS) Conference in Tennessee. The trial is ongoing.

Joint lesions were identified and assessed under arthroscopic guidance (subchondral lucencies of the medial femoral condyle of the stifle joint). These joint lesions are an indicator of early orthopaedic developmental disease in Yearling Thoroughbreds and can lead to bone cysts. The smaller lesions with less loose cartilage were subsequently injected with CryoShot Equine alone (Group 1), whereas the larger lesions, also treated with CryoShot were stabilized surgically with PDS pins to prevent cartilage movement (Group 2). Nine out of the ten lesions (90%) in Group 1 improved with a large reduction in size of the lesion. Seven out of eight lesions (88%) in Group 2 improved, with similarly large reductions in size of the lesion. One lesion in each group (~10%) progressed to bone cyst. This compares favourably with conventional therapy where only 55% improve, and up to 25% progress to bone cyst.

Up to 15% of Yearling Thoroughbreds develop abnormal subchondral lucencies in the stifle joint, with the current treatment of choice, an injection of corticosteroids under arthroscopic guidance. Although 2 in 3 improve with corticosteroids, 1 in 5 of these lucencies still progress to form a bone cyst which are a potential cause of future lameness and are associated with a reduced ability to start a race. This treatment could have a significant economic impact in the industry since horses that develop a bone cyst or having a significant lucency of the medial femoral condyle typically sell for only 30-40% of the estimated value. Considering prices at major Yearling sales are in the range of $135k[1], - $290k[2] for the better sales there are clear economic benefits in reducing the number of horses presenting to sale with obvious radiographic pathology in this area.

"We're getting better at treating these conditions and the addition of CryoShot to our treatment of conditions of the medial femoral condyle in young growing horses appears to be offering a clear advantage," said Chris O'Sullivan. "This all equates to an improved treatment of these subchondral lucencies and subchondral bone cysts providing a healthier joint, and a horse that will not be discounted at the sale-yard."

"Many people are aware that stem cells have anti-inflammatory effects. However these results indicate that in orthopaedic developmental disease, early use of mesenchymal stem cells, even before clinical signs are evident, can have a positive effect upon healing and disease progression," said Duncan Thomson, Head of the Veterinary Business for Regeneus. "The horse is often touted as a good model for

[1] http://www.magicmillions.com.au/calendar/2015-gold-coast-yearling-sale/
[2] http://inglis.com.au/sales/info/2015+Australian+Easter+Yearling+Sale/stats

human joint and bone diseases. These results encourage us to explore earlier use of cell therapy for people with developmental orthopaedic diseases."

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About Regeneus:
Regeneus Ltd (ASX: RGS) is a clinical-stage regenerative medicine company developing a portfolio of 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 diseases.

About Randwick Equine Centre:
Randwick Equine Centre (REC) is a leading equine veterinary practice with a team of veterinarians who exclusively treat horses including specialists in the fields of surgery, medicine and anesthesia. REC's hospital uses state of the art equipment and has tested the latest therapies including cell based regenerative therapies.

Appendix

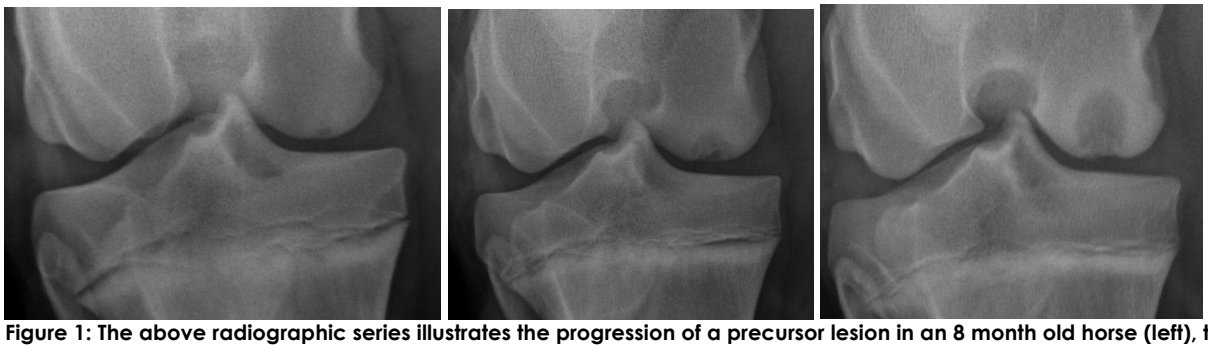

Figure 1: The above radiographic series illustrates the progression of a precursor lesion in an 8 month old horse (left), the same joint at 11 months (middle), and then at 16 months old (right).

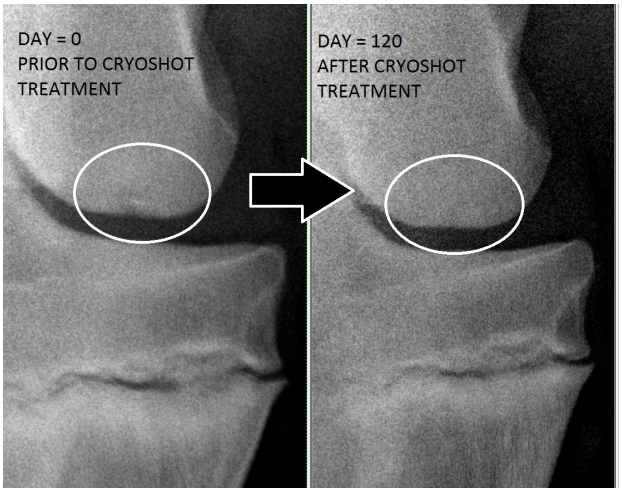

Figure 2 - The above radiographic series is from one of the horses in the trial with the initial radiograph (left) showing a significant subchondral bone defect (dark region) prior to treatment with CryoShot. The second radiograph (right) shows the same area 120 days post CryoShot injection with near complete resolution of the subchondral bone defect.

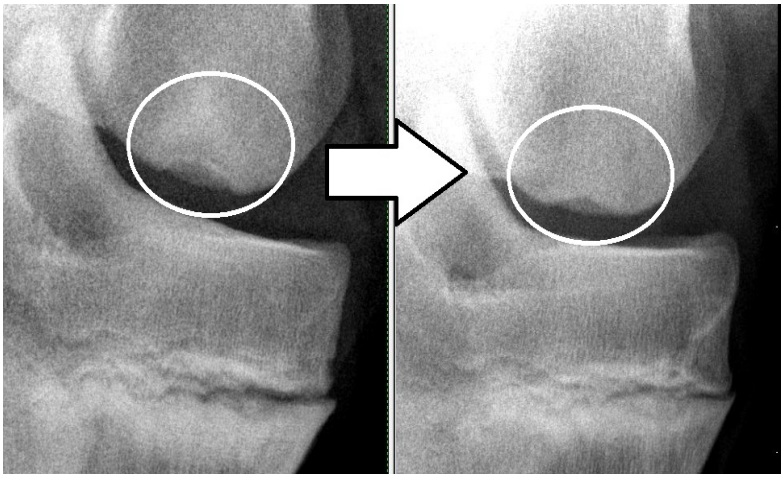

Figure 3: The first radiograph (Prior to treatment) shows significant subchondral bone defect (dark region) extending beyond the subchondral bone with significant bone sclerosis (white region) overlying prior to treatment. The second radiograph (Post treatment with CryoShot and PDS pins) shows the same area 6 months post treatment with restoration of the subchondral bone plate and resolution of the bone defect deep to it.

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