

ASX ANNOUNCEMENT

First patient safely treated in cancer vaccine trial

Sydney, Australia – 27 October 2015

Regeneus (ASX: RGS), a clinical-stage regenerative medicine company, today announced that the first patient has been enrolled and safely treated in the first clinical trial of RGSH4K, the company's autologous tumour vaccine product for the treatment of solid tumours.

A review of the first, or sentinel, patient's safety data by the study safety oversight committee identified no safety concerns. The data covered a dosing period of 2 vaccinations, administered 3 weeks apart.

The dosing of the first patient in the trial achieves a significant milestone in the clinical development of the company's vaccine therapy. The study, known as the ACTIVATE study, is a single centre, open label, first-in-human, Phase 1 dose escalating study to evaluate the safety, tolerability and preliminary efficacy of RGSH4K, administered in 21 patients with advanced cancers.

Enrolment is now open to the three different dose cohorts comprising 7 patients each for a total of 21 patients. The second and third cohorts will also include sentinel patients with a similar safety data review. Patients will be on study for 24 weeks with an option to continue dosing and long term follow up in an open-ended extension phase.

The vaccine, known as RGSH4K is produced from a patient's own cancer cells and an immunostimulant that is designed to activate the immune system against the cancer cells to initiate a body-wide response. The immune system's memory should recognise and respond to both existing and new tumours.

"We are pleased to see no safety concerns from the first treated patient. We are now focusing on enrolling more patients for this novel therapy" said Professor Stephen Clarke one of the Principal Investigators of the study.

To facilitate the trial, Regeneus has established an ethics-approved tumour bank. Participants in the trial store a tumour sample in order to produce an autologous cancer vaccine for the individual patient's use in the trial. To date, nine (9) patients have banked tumour with a view to trial enrolment. Further detail in relation to the trial and the tumour bank can be found on the [Australian New Zealand Clinical Trials Registry website](#).

The Principal Investigators for the trial are leading medical oncologists, Professor Stephen Clarke and Associate Professor Nick Pavlakis from University of Sydney's Northern Clinical School at the Kolling Institute of Medical Research located at Royal North Shore Hospital in St Leonards, Sydney. The trial is being conducted through the Northern Cancer Institute in St Leonards.

The cancer vaccine technology was developed at the Bill Walsh Translational Cancer Research Laboratory which is part of the Kolling Institute of Medical Research and is the research arm of the Medical Oncology Department, Royal North Shore Hospital.

Regeneus has the exclusive worldwide rights to develop and commercialise the vaccine technology for human and veterinary applications.

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About Regeneus:

Regeneus Ltd (ASX: RGS) is a clinical-stage regenerative medicine company developing a patented portfolio of cell-based therapies to address significant unmet medical needs in the human and veterinary health markets with a focus on osteoarthritis and other musculoskeletal disorders, oncology and dermatology diseases.

The company has two product candidates in Phase 1 trials: Progenza is an allogeneic "off-the-shelf" adipose stem cell therapy to treat osteoarthritis and other musculoskeletal conditions and RGS4K is a human autologous therapeutic cancer vaccine to treat a wide range of cancer types. The company has a stem cell secretions based cream targeting acne and other inflammatory skin conditions. The company has two therapies targeting animal conditions: CryoShot is a clinical-stage allogeneic "off-the-shelf" adipose stem cell therapy for the treatment of canine and equine osteoarthritis and other musculoskeletal conditions and Kvax is an autologous therapeutic cancer vaccine in clinical trials.

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