

ASX ANNOUNCEMENT

Regeneus receives approval for personalised cancer immunotherapy trial

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Regeneus (ASX: RGS), a clinical stage regenerative medicine company, has received ethics approval to commence its first-in-human trial for a personalised therapeutic cancer vaccine that is aimed at harnessing the body's own immune system to fight cancer cells.

The vaccine, known as RGSH4K, is produced from a patient's own cancer cells and, combined with a proprietary immunostimulant, 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.

The trial has its genesis in promising results in canines. In canine trials, Regeneus worked with the Bill Walsh Translational Cancer Research Laboratory at Royal North Shore Hospital. The vaccines, created using a dog's own tumour, resulted in the majority of treated dogs outliving the average expected survival time for their particular type of cancer.

"We are hopeful that the success we have seen with the vaccine in treating a wide variety of cancers in dogs translates to humans" said Regeneus CEO, John Martin.

Cancer immunotherapies represent a treatment option without many of the side effects of standard chemotherapy. Cancer vaccines interfere minimally with most chemotherapeutic drugs making them likely helping agents to traditional therapies. The RGSH4K vaccine is simple to manufacture and contains no live cancer cells.

The study known as the ACTIVATE trial, 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.

To facilitate the trial, Regeneus has established an ethics-approved tumour bank. Participants in the trial will need to have stored a tumour sample which then may be used to produce an autologous cancer vaccine for individual patient's use in the trial. Further detail in relation to the trial and the tumour bank can be found on the Australian New Zealand Clinical Trials Registry www.anzctr.org.au

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 will be 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. "It's exciting to see world-class innovative cancer research done at the Kolling Institute translated into clinical application as a potential new therapeutic cancer vaccine," Professor Clarke said.

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

Additional information on the human trials:

In this trial, adult patients with a variety of advanced cancer types will be treated using this revolutionary technology. The process will work as follows:

1. Suitable patients will have their tumour removed and stored (known as tumour banking) prior to commencing first-line treatment.
2. If the patient relapses, and there are no other useful treatment options available, they will move into the next stage of the trial and, using their excised tumour, have a personalised vaccine produced.
3. The personalised, or autologous vaccine, will be injected at staged intervals and patients monitored for a response.

Professor Clarke says the aim will be for the cancer to be stabilised and the tumour to shrink. Ideally this would then lead to an extended life expectancy for the patient, similar to the results obtained in the canine research.

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About Regeneus:

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

The company has four therapies targeting human conditions in various stages of development including two products approved for first-in-human Phase I trials: Progenza is an allogeneic off-the-shelf adipose stem cell therapy to treat musculoskeletal conditions and RGSH4K is a human autologous personalised therapeutic cancer vaccine to treat a wide range of cancer types. The company has a stem cell secretions based cream targeting inflammatory skin conditions and HiQCell is a marketed autologous therapy for the treatment of musculoskeletal conditions. The company has two therapies targeting the animal health market: CryoShot is a clinical-stage allogeneic off-the-shelf adipose stem cell therapy for the treatment of canine and equine musculoskeletal conditions and Kvax is an autologous personalised therapeutic cancer vaccine in marketing trials.