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ASX Announcement

Cancer vaccine trial meets primary endpoint of safety with promising signs of immune response

Sydney, Australia – 30 July 2018

Key points

- Primary endpoint of safety and tolerability met
- Immune response detected at all dose levels

Regeneus (ASX: RGS), a clinical-stage regenerative medicine company, today announced positive results from its Phase 1 safety trial of its cancer vaccine which met the primary endpoint of safety and tolerability. The study known as the ACTIVATE trial, is the first clinical trial of RGSH4K, the company's autologous tumour vaccine product for the treatment of solid tumours.

The single centre, open label, first-in-human Phase 1 study was designed to evaluate the safety and tolerability of RGSH4K and to identify the biologically active dose(s) to take into future trials. In this study,12 patients, heavily pretreated with chemotherapy or radiotherapy, with various advanced solid tumours received RGSH4K in 3 dose cohorts. A total of 3 vaccines were administered in the treatment phase, given at 3-week intervals, and patients had the option to continue dosing in an extension phase. All dose levels were safe and well tolerated, achieving the safety primary endpoint. There were no dose limiting toxicities and no serious adverse events related to the vaccine. Injection site reactions were the most common adverse event related to RGSH4K administration.

RGSH4K also showed encouraging signs of immune stimulation in some patients, as demonstrated by changes in cancer markers, immune cells and cytokines. This immune stimulation was seen in one or more patients at all three dose levels. Preliminary indications of anti-tumour activity were seen in some patients however long term follow up on 50% of the patients continues.

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 was conducted through the Northern Cancer Institute.

Professor Clarke said: "The immune response, including favourable changes in biomarkers, coupled with the benign safety profile for RGSH4K encourages proceeding to further clinical evaluation either as a single agent or in combination with other therapies."

Regeneus CEO, John Martin said: "Data obtained from this first-in-human clinical study, including the preliminary evidence of clinical activity, is encouraging and highlights the clinical potential of RGSH4K. We are pleased with these results and we will use them to advance further studies and our partnering discussions with interested parties."

About RGSH4K technology

The vaccine, known as RGSH4K, is produced from a patient's own cancer cells and, combined with an 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 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 Sydney-based clinical-stage regenerative medicine company using stem cell and immuno-oncology technologies to develop a portfolio of novel 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.