

PRESS RELEASE

Regeneus initiates canine cancer vaccine trial on lymphoma at SASH

Sydney, Australia – 26 November 2015

Regeneus (ASX: RGS), a clinical-stage regenerative medicine company, announced today the commencement of a trial of its cancer vaccine technology, Kvac, in combination with chemotherapy as a treatment for canine lymphoma. Veterinary oncologists at the Small Animal Specialist Hospital (SASH) in Sydney will conduct the trial. SASH is a leading specialist veterinary referral hospital which is often featured as the referral hospital on the television program Bondi Vet.

The trial will use Kvac together with chemotherapy to seek to extend remission times for 45 dogs with lymphoma. All dogs will be definitively diagnosed for B-cell lymphoma and will undergo chemotherapy. Once in remission the dog may then be treated with Kvac. Blinded reviewers will measure lymph nodes and time of remission and survival time will be determined. Remission lasts on average 8-10 months with chemotherapy, with a median survival time of approximately 1 year.

Kvac uses the removal of a small amount of tumour or biopsy from the patient as source material to produce a personalised cancer vaccine. The vaccine stimulates the dog's immune system to see the cancer cells as foreign and can prevent further growth of the tumour as well as development of new tumours.

Lymphoma is responsible for 7-14% of all canine cancers¹ with an estimated annual incidence rate of approximately 90 per 100,000 dogs.² Canine lymphoma is often compared to, and used as a model for non-Hodgkins lymphoma in man.³

"We're very excited to be investigating Kvac in this trial" says Dr. Veronika Langova leading veterinary oncologist at SASH, and principal investigator for the study. "Chemotherapy works well for lymphoma, but invariably the cancer will return. An improvement in remission times would be a fantastic outcome."

"Lymphoma is the most commonly treated canine cancer", said Duncan Thomson – Head of the Veterinary Business Unit for Regeneus. "A result here will undoubtedly help dogs world-wide in the fight against this terrible disease, and may also point the direction for human research."

Kvac has now been used to treat >100 dogs in Australia with >14 different types of cancer with promising results. The Kvac trial for osteosarcoma (bone cancer) conducted by VCA in the USA has been fully recruited and is ongoing. To date there have been no safety concerns with Kvac. Human Phase 1 trials of the human equivalent cancer vaccine technology, RGSH4K, are progressing.

¹ <https://vet.purdue.edu/pcop/canine-lymphoma-research.php>

² Dobson, J. M., SAMUEL, S., MILSTEIN, H., ROGERS, K., & Wood, J. (2002). Canine neoplasia in the UK: estimates of incidence rates from a population of insured dogs. *Journal of Small Animal Practice*, 43(6), 240-246.

³ <https://ccrod.cancer.gov/confluence/display/CCRCOPWeb/Non-Hodgkin's+Lymphoma>

Researchers at the Kolling Institute of Medical Research (KIMR), located at Royal North Shore Hospital in Sydney, developed the technology. In a pre-clinical rat glioma (brain tumour) model conducted at KIMR, the vaccine led to remission rates of 30%-60% and upon re-challenge these animals did not get the disease, which indicates acquired immunity. The results of this work were published in March 2014 in *Cancer Immunology Research*, the peer-reviewed journal published by the American Association for Cancer Research.

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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 veterinary health markets with a focus on osteoarthritis and other musculoskeletal disorders, oncology and dermatology diseases.

About SASH:

SASH is a purpose built animal referral hospital located in North Ryde, Sydney Australia, and has a team of dedicated veterinary specialists that work together to provide high quality and compassionate care for pets.