

PRESS RELEASE

Novel canine cancer vaccine gets green light for commercialisation in USA

Sydney, Australia – 14 November 2013

Regenerative medicine company, Regeneus, announced today that it has received written confirmation from the Center for Veterinary Biologics at the US Department of Agriculture that it can proceed with the commercialisation of its novel canine cancer vaccine in the USA. The cancer vaccine uses a dog's own tumour proteins as the source of the biological therapy.

"This is exciting news as it means we have an accelerated pathway to make our autologous vaccine available to treat dogs with life threatening cancerous tumours in the USA" said Dr Duncan Thomson, Head of Veterinary Health at Regeneus. According to the National Canine Cancer Foundation, cancer accounts for almost half of the deaths of pets over 10 years of age, which is roughly the same rate as humans. "The next step is to finalise the planning and initiate our US based marketing study which will generate important data to support the commercialisation of the cancer vaccine. The study is scheduled to commence in early 2014."

The vaccine involves removal of a tumour or biopsy from the dog in order to produce a personalised vaccine. The vaccine stimulates the dog's immune system to see the cancer cells as foreign and helps prevent further growth of the tumour as well as development of new tumours.

The technology was developed by Professor Ross Davey and Dr Chris Weir at the Bill Walsh Translational Cancer Research Laboratories which is part of the Kolling Institute of Medical Research (Kolling) at the Royal North Shore Hospital in Sydney. Regeneus has an exclusive worldwide licence for commercialisation of the technology for veterinary applications and an option over all human applications.

The vaccine has been through extensive pre-clinical testing at the Kolling which demonstrated that it could induce remission or significantly slow tumour growth in an aggressive glioma animal model. The Kolling research will be published in a peer reviewed journal in early 2014.

Since March 2011, Dr Weir has prepared as part of an ethics approved study, personalised vaccines to treat 40 dogs with a range of life threatening tumours. Cancers treated include melanoma, bone cancer and liver cancer. Dr Weir said: "the study demonstrated that there were no adverse side effects from the vaccine and over 80% of dogs treated had increased survival times as compared to published survival data for these types of cancer. I'm confident that we'll see positive results from the controlled study planned for early next year."

Professor Graham Vesey, CEO of Regeneus said: "the success of the vaccine to date in a variety of hard to treat cancers in dogs bodes well for a clinical study of the vaccine for human cancer in the near future."

END

Contact:

For more information contact Regeneus on +61 2 9499 8010, email: info@regeneus.com.au or go to www.regeneus.com.au



About Regeneus:

Regeneus is an Australian based ASX listed (ASX:RGS) regenerative medicine company which develops and commercialises technologies for making innovative autologous (patient's cells) and allogeneic (donor cells) cell therapies for the treatment of musculoskeletal, oncology and other inflammatory conditions in humans and animals.

About Bill Walsh Translational Cancer Research Laboratories:

Located on the grounds of Royal North Shore Hospital in Sydney, the Bill Walsh Translational Cancer Research Laboratories are part of the Kolling Institute of Medical Research which is affiliated with The University of Sydney's Sydney Medical School – Northern and is the principal centre of health and medical research for the Northern Sydney Local Health District.

The Bill Walsh Translational Cancer Research Laboratories are the research arm of the Medical Oncology Department at Royal North Shore Hospital. The Laboratories research activities are strongly focused on improving cancer treatment, undertaking preclinical studies that can then be fast-tracked into clinical practice.