

ASX Announcement

Kvax canine cancer treatment now available to Australian dog owners, US marketing trial starts

Sydney, Australia – 11 September 2014

Highlights

- Canine cancer therapeutic, Kvax now available via Australian vets
- Kvax provides a new personalised therapy, which is specifically created to treat individual cancer cases
- Product release follows the publishing of positive safety and efficacy data in early 2014
- Recruitment commences for Kvax US marketing trial, to provide further efficacy data, and increase awareness of Kvax with US vets and dog owners

Kvax launched with Aussie vets

Regenerative medicine company, Regeneus (ASX: RGS) today announced that it had officially launched its Kvax canine cancer treatment within the Australian veterinary market.

Kvax is considered a therapeutic cancer vaccine. A small amount of tumour from the dog is removed and sent to Regeneus' production facility, where a personalised vaccine is created using the dog's own tumour as source material. The vaccine is then administered at three-week intervals over a 12-week period, stimulating the dog's immune system and enabling it to see the cancer cells as foreign. This process helps to prevent further growth of the existing tumour, and the development of new tumours.

Release to market of Kvax follows the safe treatment of a large number of Australian dogs, and demand from vets and veterinary oncologists.

"Some of the patients treated with Kvax have shown amazing results", says Dr Miles Alexander – Veterinarian at Castle Hill Veterinary Practice and one of the early adopters of the Kvax technology. "It's great to have a new treatment option for cancer in dogs."

Dr Duncan Thomson – Head of the Veterinary Business Unit for Regeneus commented, "the Regeneus team is delighted to have brought Kvax to market so quickly with thanks to the excellent team at the Kolling Institute of Medical Research at Sydney's Royal North Shore Hospital, where it was developed."

"It's estimated that cancer accounts for approximately 23% of all deaths in dogs, while in humans (according to the Australian Institute of Health and Welfare), it is slightly higher – at approximately 30%. Kvax provides dog owners with a new treatment option for their beloved animals, which has a great safety profile and can be used either as a standalone treatment, or as an adjunct to chemotherapy."

"We're excited because of the way that it works. Ultimately this treatment could provide a new option for human cancers that are difficult to treat, as well as a follow on treatment for patients who have already been through standard treatments. Everything we've seen to date has been very encouraging."

US marketing trial recruitment commenced

Today's announcement follows the publishing of positive safety and early efficacy data in early 2014 by *Cancer Immunology Research*, the peer-reviewed journal, published by the American Association for Cancer Research.

Following the Australian launch of the product, recruitment has commenced in a US marketing trial for Kvax with VCA, a leading provider of pet health care services in the United States (US).

The trial will provide important efficacy data in a single, defined tumour type, and increase awareness of the Kvax cancer treatment with vets and dog owners in the US.

Commencement of the trial follows the receipt in late 2013 of written confirmation from the Center for Veterinary Biologics at the US Department of Agriculture that Regeneus could proceed with plans to commercialise the vaccine in the US, and the subsequent appointment of Hennessy Research to manufacture the product for the US market.

For further information regarding Regeneus and its activities, please contact the persons listed below, or visit www.regeneus.com.au, or www.kvax.com.au.

ENDS

Investors:

Sandra McIntosh
Company Secretary
Regeneus Ltd
T: +61 2 9499 8010
E: investors@regeneus.com.au or go to www.regeneus.com.au

Veterinary Health:

Duncan Thomson
Head of Veterinary Business Unit
Regeneus Ltd
T: +61 2 9499 8010
Mobile: 0428 001 496
E: duncan.thomson@regeneus.com.au or go to www.regeneus.com.au

About Regeneus:

Regeneus Ltd (ASX: RGS) is a Sydney-based ASX listed regenerative medicine company that develops and commercialises stem cell and other biological therapies for the human and veterinary health markets with a focus on musculoskeletal and oncology conditions. The company has a marketed autologous (patient's cells) product using adipose (fat) derived stem cells to treat human osteoarthritis (OA), HiQCell, which has been used to treat over 1000 arthritic joints. The company plans to commence a clinical trial of allogeneic (donor cells) adipose stem cells to treat human OA in Q2 2015.

Regeneus' lead product for the veterinary health market is CryoShot, a clinical stage allogeneic adipose stem cell product for the treatment of canine and equine OA. CryoShot Canine is scheduled for a US registration trial in Q4 2015. Regeneus has a clinical stage autologous therapeutic cancer vaccine, Kvax, which has commenced marketing trials in the US and Australia.. The company has also acquired in July 2014 the exclusive rights to commercialise the vaccine technology for human applications and plans to commence a first-in-man study in Q1 2015.

About Cancer:

Cancer is an important disease and is a major cause of death in companion animals. Its prevalence continues to rise for a variety of reasons including animals living longer, thanks to increasing care offered by caregivers and the advanced veterinary care that they seek.

45% of dogs that live to 10 years or older die of cancer¹. In a study published within Small Animal Clinical Oncology, 23% of patients that presented for necropsy had died from cancer.² The skin and soft tissues were the most common sites for tumour incidence (1,437/100,000 dogs)³, followed by mammary, urogenital, lymphoid, endocrine, and alimentary sites. Cancer was by far the largest health concern of owners (41%) with heart disease a distant second (7%).

In humans in 2010, the risk of developing cancer before the age of 85 years was 1 in 2 in men and 1 in 3 in women, while cancer accounted for about 3 of every 10 deaths (30%) registered in Australia.⁴

In 2012, cancer was estimated to be the leading cause of burden of disease in Australia, accounting for approximately 19 per cent of the total disease burden⁵.

¹ Animal health Survey. In Companion animal news, Englewood, Colorado, 1998 and 2005, Morris Animal Foundation.

² Small Animal Clinical Oncology (5th Ed) Withrow S, Vail D, Page R.

³ Dobson, J., 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.

⁴ <http://www.aihw.gov.au/cancer/>

⁵ <http://canceraustralia.gov.au/affected-cancer/what-cancer/cancer-australia-statistics>