

PRESS RELEASE

Regeneus secures exclusive worldwide rights for new therapeutic human cancer vaccine

Sydney, Australia – 8 July 2014

Regenerative medicine company, Regeneus (ASX: RGS) announced that it has signed today an agreement with Northern Sydney Local Health District (NSLHD) for the exclusive worldwide rights to develop and commercialise a new personalised therapeutic human cancer vaccine. The technology was developed at the Bill Walsh Translational Cancer Research Laboratory which is part of the Kolling Institute of Medical Research at Royal North Shore Hospital in Sydney.

“We have secured the rights for human applications of the cancer vaccine technology following pre-clinical efficacy data and promising safety data generated from the treatment of a variety of dogs with a wide range of cancer types,” said Professor Graham Vesey, CEO of Regeneus.* Regeneus holds the exclusive worldwide commercialisation rights of the vaccine technology for veterinary applications.

The production of the cancer vaccine for an individual patient requires a patient tumour sample obtained either by complete surgical removal or by small biopsy. This approach is a truly personalised therapeutic cancer immunotherapy.

Regeneus will fund a first-in-man trial (safety study) scheduled to commence in the first quarter of 2015 and further research at the Bill Walsh Cancer Research Lab to support the trial. Leading oncologists Professor Stephen Clarke and Associate Professor Nick Pavlakis, from the University of Sydney’s Northern Clinical School at the Kolling Institute, will be the investigators on the trial. “Following the positive results we have seen in canines, this has been an encouraging prelude to undertaking a human clinical trial. It’s exciting to see world-class innovative cancer research done at the Kolling Institute translated into the clinic as a potential new therapeutic cancer vaccine,” Professor Clarke said. The trial design and target tumour type will be finalised prior to seeking ethics approval.

“The therapeutic vaccine has the potential to target a wide range of hard-to-treat cancers with a single product. As the vaccine uses the patient’s own tumour cells and can be prepared under the supervision of the treating clinician, the local regulatory environment for biological therapies in Australia may allow for an accelerated clinical pathway for the autologous cancer vaccine removing the need for expensive and time consuming phase III trials” said Professor Vesey.

Under the Licence Agreement, Regeneus is responsible for the clinical and commercial development of the cancer vaccine for human applications and will pay royalties to NSLHD on the commercial use of the product.

Over the last few years there has been an increased focus on therapeutic vaccines with the US Food and Drug Administration approving the first therapeutic vaccine for cancer in 2010. There is a growing pipeline of therapeutic vaccines for an array of chronic conditions including cancer. The market for therapeutic vaccines is projected to grow at 55% per year reaching \$13billion in revenues by 2018.**

**Cancer Immunology Research*, a peer-reviewed journal of the American Association for Cancer Research, published this trial data in February 2014.

**Oliver Wyman’s MedTRACK analysis, 2012.

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About Regeneus:

Regeneus Ltd (ASX: RGS) is a Sydney-based ASX listed regenerative medicine company that develops and commercialises novel autologous (patient's cells) and allogeneic (donor cells) cell therapies for humans and animals. The company has a marketed autologous 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 adipose stem cells to treat human OA in H1 2015.

Regeneus' lead product for the animal health market is CryoShot, a clinical stage allogeneic adipose stem cell product for the treatment of canine and equine OA. CryoShot is scheduled for a US registration trial in H12016. Regeneus also has a clinical stage autologous therapeutic cancer vaccine, Kvax, which will commence marketing trials in the US and Australia in Q3 2014.

About Bill Walsh Translational Cancer Research Laboratory:

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