

## ASX Announcement

### Regeneus partners with leading animal health company on stem cell therapy for dogs

Sydney, Australia – 2 November 2015

Regeneus (ASX: RGS), a clinical-stage regenerative medicine company, announced today that it had entered into an agreement with one of the world's top 5 animal health companies to partner the development and commercialisation of CryoShot Canine. CryoShot is a proprietary "off-the-shelf" allogeneic stem cell therapy for dogs with osteoarthritis (OA) and other musculoskeletal conditions developed by Regeneus that has undergone extensive successful field trials in Australia.

Under the terms of the agreement, the animal health partner will jointly fund a pre-pivotal study assessing CryoShot as a treatment for canine osteoarthritis in consideration for an exclusive option to develop and commercialise CryoShot Canine.

Professor Dorothy Brown, who leads the Veterinary Clinical Investigations Center at the University of Pennsylvania School of Veterinary Medicine, will be the principal investigator on the study. The study, which commenced on 2 November 2015, will assess pain and dysfunction in eighty (80) arthritic, client owned dogs. Dogs will be treated with CryoShot Canine via intra-articular injection, or a control and will be assessed by validated questionnaires and force-plate analysis. The results of the trial will be used to finalize the design of a pivotal US Food and Drug Administration (FDA) trial with good manufacturing practice (GMP) grade product. The results of the study are anticipated in Q3 2016.

Upon completion of the study, the animal health partner has a period in which to exercise its option to enter into an exclusive licence over the CryoShot technology. Under the terms of the licence, Regeneus will receive an upfront licence fee and be entitled to other development milestone payments to be agreed at the time. The animal health partner will be responsible for funding the pivotal study and GMP manufacture of CryoShot and have exclusive global rights for sales and marketing for canine applications. Regeneus will receive a royalty on all CryoShot sales.

"Our vision is to make CryoShot one of the first allogeneic off-the-shelf stem cell therapies available for the treatment of canine osteoarthritis. We're delighted to have a world-leading animal health company that shares this vision, as well as a veterinary pain specialist of Professor Brown's calibre leading the study" said Duncan Thomson, Head of Animal Health at Regeneus.

Osteoarthritis is the dominant musculoskeletal condition in dogs and is associated with pain and degeneration of joint tissues. Non-steroidal anti-inflammatory drugs (NSAIDs) are the mainstay treatment for pain associated with OA. The companion animal pain market has been estimated to be USD\$260m in the US alone, while the global pain market is in the region of USD\$0.5b per annum.

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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.

The company has two product candidates in Phase I trials: Progenza is an allogeneic "off-the-shelf" adipose stem cell therapy to treat osteoarthritis and other musculoskeletal conditions and RGSH4K is an autologous therapeutic cancer vaccine to treat a wide range of cancer types. The company is developing a stem cell secretions based cream targeting acne and other inflammatory skin conditions. The company has two therapies targeting animal conditions: CryoShot is a clinical-stage allogeneic off-the-shelf adipose stem cell therapy for the treatment of canine and equine osteoarthritis and other musculoskeletal conditions and Kvax is an autologous therapeutic cancer vaccine in clinical trials.