regeneus
living regenerative medicine

ASX Announcement

Regeneus 2018 Full-Year Results and Business Update

Sydney, Australia – 30 August 2018

- Significant progress on supporting AGC's future manufacture of Progenza to a commercial scale in Japan
- Advanced discussions to secure a Japanese partner for the Phase 2 trial of Progenza and its clinical development and commercialisation in Japan
- Positive results from Phase 1 Safety Trial of Progenza showing safety, pain reduction and disease modification in patients with knee osteoarthritis published in the Journal of Translational Medicine
- US Patent to be granted for the composition, manufacture and use of Progenza
- Progenza granted Europe's Advanced Therapy Medicinal Therapy (ATMT) classification, recognising it as a regenerative therapy within European Union's legal and regulatory framework
- Sygenus delivers positive results in preclinical pain study, showing strong analgesic affect
- Sygenus gel found to significantly reduce the appearance of acne lesions and significantly lighten the colour and reduce the size of age spots
- Phase 1 ACTIVATE trial of cancer vaccine immunotherapy technology meets primary endpoints for safety and tolerability with encouraging signs of immune stimulation

Regeneus Ltd (ASX: RGS) (**Regeneus** or **the Company**), a clinical-stage regenerative medicine company, is pleased to provide an overview of its results for the financial year ended 30 June 2018.

The Company achieved a number of major milestones during the period across its Progenza, Sygenus and RGSH4K technologies, and is poised to secure its next licensing partner for the clinical development and commercialisation of Progenza in Japan.

Strategic Collaboration with AGC Progresses Towards Manufacturing

Strong progress has been made establishing the appropriate know-how and processes to support AGC's future manufacture of Progenza under cGMP to a commercial scale. During the period, a cell production facility was established at AGC's Yokohama Research Centre and a knowledgeable team with considerable cell therapy experience recruited. The team is able to successfully replicate the production process for the Australian STEP trial, and is now developing processes to support an increase in manufacturing capabilities to a commercial scale.

Discussions Well Advanced with Several Potential Japanese Clinical and Commercialisation Partners

Management is in the advanced stages of discussion and due diligence processes with potential licensees for the clinical development and commercialisation of Progenza in Japan. Working closely with AGC and the Company's Japanese advisors, it is anticipated that a licence agreement will be secured in Q2 FY19. The licensee will be responsible for the sponsorship and funding of the Company's Phase 2 trial of Progenza for osteoarthritis and its commercialisation in Japan and will mark a significant next milestone in the Company's progress towards commercialisation.

Positive Progenza Phase 1 Safety Trial Published in Journal of Translational Medicine

The Phase 1 Safety, Tolerability and Efficacy of Progenza (STEP) trial on patients with knee osteoarthritis (OA) delivered positive results which were published in the Journal of Translational Medicine[1] in March 2018. The trial found a single injection[2] of Progenza into the knee to be safe and well tolerated by patients, delivering durable and clinically meaningful pain relief for patients with knee OA. Progenza was shown to deliver a statistically significant improvement to lateral tibial cartilage volume in patients injected with 3.9 million cells of Progenza, compared to worsening placebo patients (p=0.028). The assessment was made from examination of the knee joint structure by MRI.

Additional Progenza Highlights Include:

- The United States Patent Office issuing a notice of allowance for a US patent for Progenza[3] in July 2018, covering the composition, manufacture and use of Progenza in the treatment of a wide range of inflammatory conditions, including osteoarthritis.
- The granting of an Advanced Therapy Medicinal Therapy (ATMT) classification by the Committee for Advanced Therapies of the European Medicines Agency, recognising Progenza as a regenerative therapy within European Union's legal and regulatory framework[4].

Sygenus Delivers Positive Results in Preclinical Pain Study

In September 2017, Regeneus released positive results of a preclinical study and the effects of Sygenus on post-operative pain. MSCs have been previously shown to improve pain through known anti-inflammatory benefits. Sygenus was shown to deliver a sustained analgesic effect, which was longer-lasting than morphine, in the first ever known demonstration of this effect from mesenchymal stem cells (MSCs) and their secretions. The Company continues to conduct preclinical studies of Sygenus and Progenza in the treatment of pain as it looks to determine optimised doses and routes of administration. A preclinical study in neuropathic pain is also underway.

Additional Sygenus Highlights Include:

- Positive results from the topical application of Sygenus gel in treating acne in adults. The gel was well tolerated and found to significantly reduce the appearance of lesions and significantly reduced patients' acne global severity score after the 6-week period.
- Positive results from the topical application of Sygenus gel to significantly lighten the colour of age spots. 95% of age spots were smaller and 63% of age spots were both smaller and lighter at eight weeks. The gel was well tolerated by patients.
- The granting of a broad Australian Patent for the topical application of Sygenus for the treatment of aging skin and age spots.
- The granting of a Chinese patent for the use of Sygenus in the topical treatment of acne, providing commercial rights in China to the year 2023.

Cancer Vaccine Phase 1 ACTIVATE Trial Meets Primary Endpoints of Safety and Tolerability

During the period, the Company completed recruitment for the Phase 1 Safety Study (ACTIVATE trial) of the Company's cancer vaccine immunotherapy technology RGSH4K across a wide range of tumours in humans.

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[1] Kuah *et al. JTranslMed (2018)* 16:49. This article is available via Regeneus' company website.
[2] Results for injections of 3.9 million cells and 6.7 million cells.
[3] US Patent Application Number 14/342479 "Therapeutics using adipose cells and cell secretions".
[4] Article 2 (4) of Regulation (EC) No 1394/2007.

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The trial is a single centre, open label, Phase 1 dose escalating study to evaluate the safety, tolerability and preliminary efficacy of RGSH4K and determine the active dose(s) to take into future trials.

During the study, a total of 3 vaccines of RGSH4K were given at 3-week intervals to 12 heavily pre-treated patients with multiple types of advanced tumours. All dose levels were safe and well-tolerated, meeting the study's safety primary endpoint, with no dose limiting toxicities and no serious adverse events related to the vaccine.

On 30 July 2018, the Company announced the ACTIVATE trial had met its primary endpoint of safety and tolerability and showed encouraging signs of immune stimulation in patients from each cohort, as demonstrated by changes in cancer markets, immune cells and cytokines, in one or more patients at all three dose levels. Some patients showed preliminary indications of anti-tumour activity, however long-term follow up of 50% of the patients continues.

Other Achievements:

- Recruitment is currently underway for pre-pivotal trial assessing Cryoshot for the treatment of canine osteoarthritis
- Recruitment continuing for Kvax canine cancer vaccine – a similar technology to RGSH4K – with early indications showing no safety concerns

Financial Overview

Financial metrics for the year ended 30 June 2018 include:

- Operating loss of $5.18m (FY17: $3.27m profit, driven by $8.9m AGC licence fee revenue), with next AGC licence milestone fee revenue due in Q2 FY19
- R&D tax incentive of $2.16m (FY17: $2.61m)
- Quarterly cash used in operations (excluding R&D tax incentive and FY17 AGC licence revenue) of $1.7m, in line with FY17
- Loan facility secured of $1.9m repayable on the earlier of receipt of next AGC milestone payment; receipt of FY19 R&D Tax incentive rebate for FY19 and 30 September 2019

Outlook

The Company remains poised to deliver on a number of important commercial, clinical and R&D milestones FY19 and into FY20, including:

- Securing its first clinical licence for Progenza in Japan
- Progressing the clinical development of Progenza for osteoarthritis in Japan
- Commencing manufacturing of cGMP Progenza in Japan under the Company's existing strategic collaboration and licensing agreement with AGC
- Securing additional licensing opportunities for Progenza in additional key territories, including the USA, China and the European Union
- Progressing the development of Progenza for specific pain indications
- Progressing the development of Sygenus for specific pain and dermatological indications
- Advancing licensing discussions for RGSH4K following positive ACTIVATE trial results
- Reporting on CryoShot canine pre-pivotal trial and advancing licensing discussions.

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About Regeneus Limited

Regeneus Ltd (ASX:RGS) is a Sydney-based clinical-stage regenerative medicine company using stem cell and immuno-oncology technologies to develop a portfolio of novel cell-based therapies to address significant unmet medical needs in the human and animal health markets with a focus on osteoarthritis and other musculoskeletal disorders, oncology and dermatology.

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