

ASX Announcement

23 July 2019

Positive preclinical trial results for Progenza in treating neuropathic pain

Highlights

- Progenza shows reversal of disease in neuropathic pain model
- A single injection of Progenza resulted in the complete reversal of symptoms of allodynia
- Trial conducted at the University of Adelaide under Professor Mark Hutchinson, as part of an Australian Research Council Linkage grant between UNSW, the University of Adelaide and Regeneus
- Regeneus continues to accelerate its growth strategy focused on the global pain market

Regeneus Ltd (ASX: RGS) (Regeneus or the Company), a clinical-stage regenerative medicine company, today announced positive results from its preclinical trial of Progenza in the treatment of allodynia, a condition in which pain occurs from what is normally non-painful stimulation of the skin, such as light touch.

The trial, completed with the University of Adelaide, assessed Progenza's ability to reverse the development of induced allodynia in the neuropathic pain model. Progenza is the Company's allogeneic off-the-shelf stem cell technology platform, developed for the treatment of pain in musculoskeletal and other inflammatory diseases.

The study showed a single injection of Progenza given on day 14 post-nerve injury was effective in gradually reversing allodynia to a level that is not significantly different than prior to injury. The preclinical results provide further validation of the significant potential for Progenza in the treatment of neuropathic pain.

Conducted under Professor Mark Hutchinson, the study was made possible via an Australian Research Council Linkage grant between UNSW, the University of Adelaide and Regeneus.

The study further supports the Company's growth strategy targeting the global neuropathic pain market, which at present, has limited successful treatment options, and many with substantial unwanted side effects such as the addictive opioid pharmaceuticals. The Company recognises the total addressable market for global pain as a significant market opportunity, with the global neuropathic pain industry alone estimated to be worth US\$69 billion and forecast to reach US\$79 Billion by 2024¹.

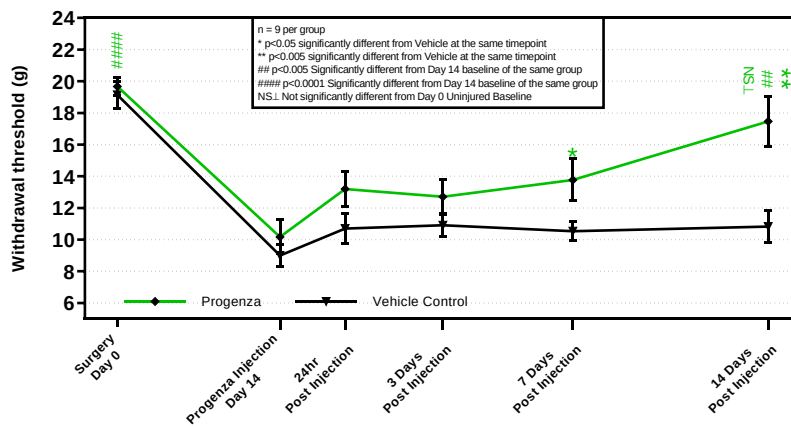
Regeneus non-executive director Dr. Alan Dunton said:

"Studies like this support the development of Progenza for treating neuropathic pain where very few options exist. This preclinical evaluation in an animal model which is well accepted for neuropathic pain, portends the real potential of Progenza as we focus on commercialising the platform internationally. Regeneus remains firmly committed to accelerating its growth strategy focused on the global pain market."

Professor Mark Hutchinson said:

"In our experience of developing pain treatment interventions, it is uncommon to identify treatments that create long-lived reversal of exaggerated pain states lasting weeks after single doses. In our model of exaggerated pain behaviours Progenza was capable of this long-term complete reversal of the exaggerated pain behaviour. This is the type of a treatment response that is highly desirable for a new therapy."

¹ Source: Datamonitor Healthcare – Neuropathic Pain Market Spotlight 2018.



Details of the Study

The study optimised the rat model which allowed for the graded measurement of neuropathic pain to match human neuropathic pain conditions. Researchers induced an injury to the sciatic nerve of the hind limb on the rats, by placing sutures around the sciatic nerve, causing allodynia to develop and become maximum at 14 days post-surgery. Allodynia is measured (blinded to treatment) in the rats by mechanical stimulation of the rat's paw and measuring the amount of force required to make the rat withdraw the paw.

For 14 days after injury the rats develop allodynia and become more sensitive to being touched. Progenza (cells) or vehicle (fresh tissue culture media) were administered by intrathecal injection on day 14. The rats treated with Progenza showed a gradual reversal of allodynia. By the fourteenth day, the trial showed they returned to a level that is not significantly different prior to surgery.

Treatment with a single injection of Progenza reversed allodynia. The results of this study will be submitted for publication in a peer reviewed journal.

About Progenza

Progenza is an allogeneic off-the-shelf stem cell technology platform developed for the treatment of osteoarthritis and other musculoskeletal diseases. It has the potential to be used for other inflammatory diseases that have limited treatment options. Made from expanded mesenchymal stem cells (MSCs) from human adipose tissue, it contains the bioactive secretions of cells. Progenza cells work by secreting cytokines, growth factors and exosomes that act in concert to reduce inflammation and pain and encourage accelerated healing and repair of damaged or diseased tissue. It is a scalable technology that has demonstrated capability to produce millions of doses of cells from a single donor.

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About Regeneus Ltd

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

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