

ASX Announcement

20 March 2024

Optimisation of Progenza Patent Portfolio

Regeneus Ltd (**Regeneus** or **Company**) is committed to optimising its patent portfolio to reduce intellectual property maintenance costs while focusing on core markets. As part of this strategy, the Company has decided to allow the following patents to lapse:

- "Stem cells and secretions for treatment of inflammatory conditions" (Australia)
- "Therapeutic methods and compositions comprising cells and secretions" (Australia)
- "Therapeutics using adipose cells and cell secretions" (Singapore, Canada, Belgium, Switzerland, Germany, Denmark, Spain, France, United Kingdom, Ireland, Italy, The Netherlands, and Sweden).

These patents pertain to the combination of adipose-derived mesenchymal stem cells and secretions used in the Progenza product for the treatment of knee osteoarthritis. The Company will continue to maintain Progenza patents in its core markets, the United States of America and Japan.

Rationale

In 2017, Regeneus conducted a Phase 1 study for Progenza using a product manufactured under non-Good Manufacturing Practice (GMP) compliant conditions. To progress to Phase 2 studies, the investigational drug must be manufactured in GMP-compliant conditions, which would require a new donor and certain modifications to the manufacturing process. These chemistry, manufacturing, and controls (CMC) changes are considered major by the FDA in the USA and other major global regulators.

Consequently, before advancing to Phase 2 studies, the Company would need to demonstrate substantial equivalency between the intended Phase 2 GMP product and the Phase 1 non-GMP product. Given this additional regulatory hurdle and the expiration of the patents in mid-2032, Regeneus believes it is unlikely that Progenza can be developed and approved in markets outside the USA and Japan within the remaining patent term.

By allowing patents to lapse in non-core markets, Regeneus can allocate resources more effectively to advance Progenza in its core markets while reducing overall intellectual property maintenance costs.

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About Regeneus

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. Regeneus' regenerative platform technologies Progenza™ and Sygenus seek to address unmet medical needs in human health markets, focusing on neuropathic pain, osteoarthritis and various skin conditions. Visit www.regeneus.com.au for more information.

Authorisation & Additional information

This announcement was authorised by the Board of Directors of Regeneus Ltd