

ASX Announcement 31 January 2022

NOTICE OF TERMINATION OF KYOCERA LICENCE

Background

As announced on 11 August 2020, Regeneus entered into a licence and collaboration agreement (**Agreement**) with Kyocera Corporation (**Kyocera**), for Kyocera to exclusively develop and commercialise Regeneus' stem cell platform technology Progenza for the treatment of Knee Osteoarthritis in Japan.

Pursuant to the Agreement Regeneus has received aggregate upfront and milestone payments of approximately AUD\$7.1M comprised as follows:

- JPY 100,000,000 upfront payment, upon signing the Agreement;
- USD\$4,000,000 milestone payments, upon delivery of the initial data package and additional data as per the Variation Agreement signed in 2021.

The Agreement included typical Development Targets and Target Dates agreed by the parties, including a Development Target related to the establishment of first Standard Operating Procedures for the manufacture of Progenza for the clinical trial to be held in Japan – which was expected to be achieved in Q4 2022 or Q1 2023. Kyocera has failed to meet this Development Target.

Under the terms of the Agreement, Kyocera has certain rights to terminate the Agreement if any Development Target is not achieved by dates specified in the Agreement. This right to terminate is subject to Kyocera using commercially reasonable efforts to achieve the applicable Development Target by the date specified.

Purported Termination Notice

Regeneus has received a notice of termination dated 27 January 2023 (**Notice**) from Kyocera under the Agreement.

The Notice purports to terminate the Agreement for Kyocera's failure to meet its Development Target relating to establishment of first Standard Operating Procedures for the manufacture of Progenza for the clinical trial to be held in Japan by the required date – being 30 September 2022.

Unless a resolution is reached between the parties, the Agreement will terminate 90 days after the date of the Notice.

Regeneus' position

The Board of Regeneus is currently considering its overall position in relation to the Notice.

Regeneus' current position is that Kyocera's lack of drug development capabilities and its allocation of insufficient resources to the development of Progenza cellular therapy for the Japanese marketplace resulted in Progenza development delays. Regeneus believes that Kyocera did not exercise commercially reasonable efforts as defined in the Agreement, and Regeneus is currently considering its further legal options in this regard.

Regeneus has communicated to Kyocera that Regeneus:

- does not accept that Kyocera has any right to terminate the Agreement;
- considers that Kyocera is in material breach of its obligations under the Agreement, as a result of its failure to exercise commercially reasonable efforts to achieve the applicable Development Target by the date specified; and
- considers that the failure to meet the Development Target is due to Kyocera's failure to fulfil its own obligations under the Agreement.

It is important to note that Kyocera's failure to meet the Development Target is not due to any failure by Regeneus to meet its own obligations under the Agreement.

The parties have initiated the dispute resolution process under the Agreement. The Board will continue to update Regeneus shareholders, and the market generally, as these dispute resolution procedures are carried out by the parties.

Karolis Rosickas, Regeneus' CEO commented: "Regeneus remains committed to the development and commercialisation of Progenza. It is extremely disappointing that, after having invested so much in the relationship with Kyocera over the last 2 ½ years, and having fully complied with all of its own obligations under the Agreement, Regeneus finds itself in a position of considering its rights and the enforcement of those rights under the Agreement."

-ENDS-

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

Authorisation & Additional information

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

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