

ASX Announcement
11 August 2020

Regeneus and Kyocera sign Progenza OA licence and collaboration agreement

Highlights:

- Regeneus and Kyocera have signed a licence and collaboration agreement for Kyocera to exclusively develop and commercialise Regeneus' lead stem cell platform technology Progenza for the treatment of Knee Osteoarthritis (Knee OA) in Japan
- Regeneus to receive US\$19m (A\$27m) in upfront, development and regulatory milestone payments
- Additional single to high double-digit royalties on Progenza OA product sales in Japan based on future reimbursement prices
- Kyocera will fund manufacturing, development, and commercialisation costs for Progenza OA in Japan under the agreement
- Upfront payment provides cash runway for Regeneus through to the commercial launch of Progenza OA in Japan
- The global market for osteoarthritis is expected to grow to US\$3.5 billion by 2026 with the Japanese market worth US\$350 million¹. The potential osteoarthritis patient population is 25.6 million in Japan with 1.25 million people receiving treatment, and is expected to rise each year².

Regeneus Ltd (ASX: RGS) (Regeneus or the Company), a clinical-stage regenerative medicine company, today announced that Kyocera Corporation (Kyocera, TYO:6971) has signed a licence agreement to develop and commercialise Progenza for Knee Osteoarthritis (Progenza OA) in Japan.

Progenza OA has already completed a Phase I study which met all safety and efficacy endpoints. The study demonstrated that a single injection of Progenza OA into the knee was safe, tolerable and showed significant, rapid and sustained reductions in knee pain for osteoarthritis patients, and showed positive signs of disease modification showing no deterioration in the joint following the injection.

The licence and collaboration agreement follows the two companies signing a Memorandum of Understanding (MOU) in March 2020, and Kyocera completing detailed due diligence on Progenza OA .

¹ Source: Osteoarthritis market set to be worth \$3.5 billion by 2026.

<https://www.globaldata.com/osteoarthritis-7mm-market-set-to-be-worth-3-5-billion-by-2026/>

² Japanese Government statistics and patient surveys 2017

Key highlights of the transaction

- **Licence and collaboration agreement for Japan signed with Kyocera for Progenza for Knee Osteoarthritis**
 - Regeneus grants to Kyocera a licence enabling Kyocera to exclusively develop and commercialise Regeneus' lead mesenchymal stem cell (MSC) and Secretome technology Progenza, for the treatment of Knee Osteoarthritis (Progenza OA)
 - Collaboration agreement includes technology transfer and joint research on Progenza for Japan
 - Kyocera has right of first refusal for other indications inside and outside of Japan
 - Regeneus retains rights to negotiate licences with other parties outside of Japan for other indications for Progenza
 - Regeneus retains the rights to license indications other than Knee OA with other parties in Japan
- **Upfront payments, milestone payments and royalties**
 - Regeneus will receive US\$19 million (A\$27m) in upfront and milestone payments from Kyocera consisting of:
 - US\$9 million (A\$13m) upfront payment, of which A\$2m was received as part of the MOU
 - US\$10 million (A\$14m) in regulatory and development milestone payments
 - Additionally, Regeneus will receive single to high double-digit royalties on all future Progenza OA product sales in Japan based on future reimbursement prices
 - Upfront payments expected to provide sufficient cash runway for Regeneus until the commercial launch of Progenza OA in Japan
- **Kyocera will be responsible for product development, manufacturing and regulatory activities in Japan**
 - Kyocera will be responsible for, and fund, the establishment of the manufacturing of clinical and commercial products, sponsoring clinical study for regulatory approval, all regulatory filings for drug approval and the reimbursement with Japan's National Health Insurance
- **Global addressable market for Osteoarthritis**
 - The global market for osteoarthritis is expected to grow to US\$3.5 billion by 2026 with the Japanese market worth US\$350 million³. The potential osteoarthritis patient population is 25.6 million in Japan with 1.25 million people receiving treatment and is expected to rise each year⁴.
 - Japan has a favourable regulatory environment for regenerative medicine and there is potential to fast track approval for Progenza as products can be approved for sale under specific conditions once safety and efficacy are confirmed. As previously noted, Progenza met all safety and efficacy

³ Source: Osteoarthritis market set to be worth \$3.5 billion by 2026.

<https://www.globaldata.com/osteoarthritis-7mm-market-set-to-be-worth-3-5-billion-by-2026/>

⁴ Japanese Government statistics and patient surveys 2017

endpoints in a Phase I study in 2018. Kyocera will work towards marketing approval for Progenza OA pending completion of a Phase II study.

“This agreement with Kyocera is an exciting development for Regeneus and is an endorsement of our Progenza platform technology. It provides a clear commercialisation pathway for Progenza and is a significant market given osteoarthritis potentially affects more than 25.6 million people in Japan alone⁵,” said Regeneus CEO Leo Lee.

“We look forward to working with Kyocera to take Progenza OA through the commercialisation process.”

About Osteoarthritis

Osteoarthritis (OA) is the most common form of arthritis and is often referred to the ‘wear and tear’ around the tissue of joints and is characterised by pain and inflammation. While it can damage any joint, it commonly affects joints in the knees, hands and hips. The global market for OA is expected to grow to US\$3.5 billion by 2026⁶. Progenza addresses a large, unmet patient need for Knee OA ahead of invasive surgery as it treats pain and modifies the disease

About Progenza OA

A Phase I study of Progenza in OA patients (KL Grade 1-3) demonstrated significant treatment-related reductions in pain for up to 12 months, as well as stabilisation of cartilage volume in the target dose group

Progenza's mechanism of actions turns inflammatory immune cells into anti-inflammatory cells, thereby addressing inflammation at its source. In turn this downregulates pain-causing signals and repairs damaged tissues, such as cartilage tissue, commonly found in joints such as knees and elbows

-ENDS-

About Regeneus

Regeneus Ltd (ASX:RGS) is a Sydney-based 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 neuropathic pain, including osteoarthritis and various skin conditions, with its platform technologies Progenza and Sygenus. Visit www.regeneus.com.au for more information.

About Kyocera

[Kyocera Corporation](https://global.kyocera.com/) (TOKYO:6971, <https://global.kyocera.com/>), the parent and global headquarters of the Kyocera Group, was founded in 1959 as a producer of [fine ceramics](#) (also known as “advanced ceramics”). By combining these engineered materials with

⁵ Ibid

⁶ Source: Osteoarthritis market set to be worth \$3.5 billion by 2026.

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metals and integrating them with other technologies, Kyocera has become a leading supplier of medical and dental products, industrial and automotive components, semiconductor packages, electronic devices, smart energy systems, printers, copiers, and mobile phones. During the year ended March 31, 2020, the company's consolidated sales revenue totaled 1.6 trillion yen (approx. US\$14.7 billion). Kyocera is ranked #549 on *Forbes* magazine's 2020 "Global 2000" list of the world's largest publicly traded companies.

Authorisation & Additional information

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

Investor and Media Contact

WE Communications

T: 02 9237 2805

E: WE-AURegeneus@we-worldwide.com