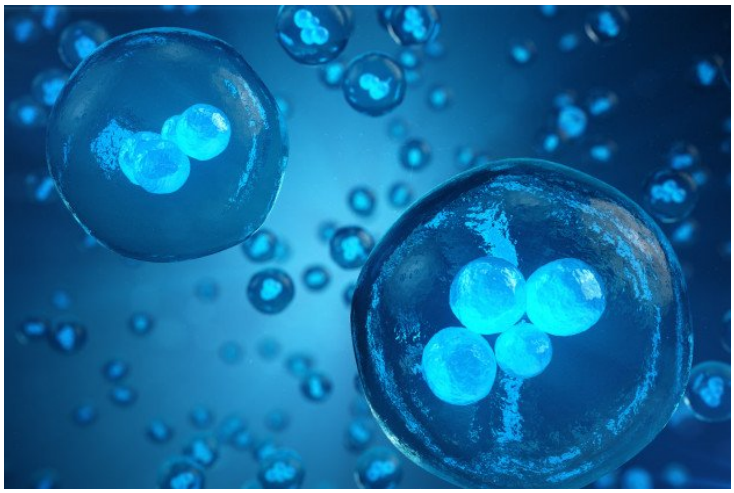
BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Regeneus, Kyocera ink $19M deal for knee osteoarthritis treatment

August 12, 2020 | News

Regeneus will receive US$19 million (A$27m) in upfront and milestone payments from Kyocera



Regeneus Ltd, an Australian clinical-stage regenerative medicine company, has announced that Japanese manufacturing giant Kyocera Corporation has signed a license agreement to develop and commercialize 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 .

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 million. The potential osteoarthritis patient population is 25.6 million in Japan with 1.25 million people receiving treatment and is expected to rise each year.
    - 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 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 endorsement of our Progenza platform technology and provides a clear commercialization pathway for Progenza and is a significant market given osteoarthritis potentially affects more than 25.6 million people in Japan alone," said Regeneus CEO Leo Lee.