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Press Release

New regenerative medicine laws to fast track cell therapy approvals take effect in Japan

Sydney, Australia - 26 November 2014

- **New Japanese regenerative medicine laws come into effect providing an accelerated path for approval of cell therapy products**
- **Regeneus is targeting Japan for its new allogeneic off-the-shelf cell therapy for knee osteoarthritis in humans (PRG)**
- **The Japanese market is well suited to an off-the-shelf cell therapy product for OA as Japan has a rapidly ageing population, there is a recognised shortage of effective non-surgical treatment options and there is a substantial market for joint injections to treat OA**
- **Regeneus is engaged with Japanese regulators, clinicians and potential manufacturing and commercialisation partners for the development of PRG**
- **PRG is on-track for its first-in-man trial in Australia during H1 2015**

Regeneus Ltd (ASX: RGS) announces that the new Japanese regenerative medicine laws that passed through Parliament in November 2013, have come into effect. These new laws reform the pharmaceutical and medical regulations related to regenerative medicine and provide a rapid approval process specifically designed for regenerative medicine products.

Regeneus CEO John Martin said, "These new laws provide the company with a unique opportunity to fast-track the clinical trial and seek approval of its new allogeneic off-the-shelf cell therapy product, PRG, to treat human osteoarthritis in the Japanese market". "We believe that the Japanese market is well suited to PRG as it has a rapidly ageing population with increased rates of bone and joint disease, there is a recognised shortage of effective non-surgical treatment options and Japan is a major market for joint injections to treat OA," said Mr Martin.

Under the new laws, once you have demonstrated safety and basic efficacy data in humans with a cell product manufactured to the Pharmaceuticals and Medical Devices Agency's **(PMDA)** standards, the cell therapy can be given conditional approval for up to 7 years for commercial use with data reporting requirements and potential for national insurance coverage. Safety data can be used from non-Japanese participants.

Since the laws were passed through the Japanese Parliament in November 2013, the company has taken key actions to pursue this opportunity including:

- engaging local advisors to complete regulatory and market analysis
- engagement with the PMDA on the operation of the new laws
- engagement with potential manufacturing and commercialisation partners in Japan
- undertaking pre-clinical and product manufacturing steps
- preparing for ethics approval and conduct of first-in-man trial for PRG in in Australia H1 2015

The company's strategy is to identify Japanese partners to help de-risk the phase II trial and product manufacture in Japan.

PRG uses donor adipose (fat) derived mesenchymal stem cells, which are manufactured by a proprietary method to optimize their potency and viability. Once injected into an arthritic joint, the stem cells used in PRG seek to embed at the site of the inflammation and secrete a range of cytokines which encourage a reduction in inflammation and induce repair and regeneration of the damaged tissue.

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About Regeneus:

Regeneus Ltd (ASX: RGS) is a Sydney-based ASX listed regenerative medicine company that develops and commercialises stem cell and other biological therapies for the human and veterinary health markets with a focus on musculoskeletal and oncology conditions. The company has a product platform that includes autologous (patient's cells) products and allogeneic (donor cells) products.

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