



Regeneus Limited

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Regeneus poised to benefit from new Japanese regenerative medicine laws

Regenerative medicine company Regeneus Limited (ASX:RGS) is well placed to benefit from new Japanese regenerative medicine laws that have come into effect and provide an accelerated path for the approval of cell therapy products.

The company has already taken key actions since the laws were passed through the Japanese Parliament in November 2013, providing it with the benefit of first mover status.

Regeneus is targeting Japan for its new allogeneic off-the-shelf cell therapy for knee osteoarthritis in humans (PRG).

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.

New laws

The new laws reform the pharmaceutical and medical regulations related to regenerative medicine and provide a rapid approval process specifically designed for regenerative medicine products.

John Martin, Regeneus CEO, said that the new laws provide the company with a unique opportunity to fast-track the clinical trial and seek approval of its new PRG product.

"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."

Regeneus is engaged with Japanese regulators, clinicians and potential manufacturing and commercialisation partners for the development of PRG.

Impact of the laws

Under the new laws, once a company has 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.

This approval can be 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.

Key points with change in regenerative medicine laws in Japan

1 Year Share Price Graph



Share Information

Code: RGS
Listing: ASX
Sector: Medical Supplies
Website: www.regeneus.com.au

Company Synopsis:

Regeneus Limited (ASX:RGS) is a Sydney based regenerative medicine company founded in August 2007 that is focused on using the regenerative capacities of adipose-derived cells to develop innovative cell therapies for humans and animals.

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- 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.

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