

PRESS RELEASE

Regeneus to fast-track human cells under new Japanese laws

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The Japanese parliament has passed new laws that provide a rapid approval process specifically designed for human stem cell therapies. Regenerative medicine company, Regeneus (**ASX:RGS**), is ready to move on the opportunity. These new laws give the company a unique opportunity to fast-track the clinical trial and potential approval of its new human “off-the-shelf” cell therapy to treat osteoarthritis and other inflammatory musculoskeletal conditions into the Japanese market.

“Japan, the second largest healthcare market in the world, is setting itself up to be a world leader in regenerative medicine by providing a clear risk-adjusted regulatory framework for swift and safe translation of regenerative medicine research to early access to the latest cell therapies that can address a range of unmet medical needs,” said John Martin, Executive Chairman of Regeneus. “These new laws will help drive innovation in the regenerative medicine space and will attract the attention of other health regulators”.

Under the new laws, there will be a separate approval channel for regenerative medicine products like cell therapies. Once you have demonstrated limited safety and efficacy data in humans, the new cell therapy can be approved for commercial use with data reporting requirements and potential for national insurance coverage.

Professor Graham Vesey, CEO of Regeneus said: “This exciting opportunity in Japan provides us with a well defined pathway to fast-track the clinical trial and potential approval of our new human off-the-shelf cell therapy to treat osteoarthritis and other inflammatory musculoskeletal conditions”.

“CryoShot® is our off-the-shelf cell therapy platform and the canine and equine versions have been used to treat over 2000 dogs and horses with osteoarthritis in extensive field trials in Australia. The results have been very encouraging and we anticipate the canine CryoShot product entering into an FDA approved trial for canine osteoarthritis in 2014”, said Professor Vesey.

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

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About Regeneus:

Regeneus (**ASX:RGS**) is an Australian regenerative medicine company that develops and commercialises innovative cell-based therapies using its proprietary cell technologies with a focus on treating musculoskeletal, oncology and other inflammatory conditions in humans and animals