

Regenerative medicine



More than 3.9 million Australians suffer from arthritis.

New hope for osteoarthritis sufferers

"The pain in my knee is crippling. It keeps me awake at night and stops me doing the things that I love ..."

This is a common complaint of osteoarthritis sufferers, according to Dr Donald Kuah, a leading sports medicine specialist in Sydney.

"Osteoarthritis is a progressive disease," he says. "The symptoms may vary, but the destruction of cartilage gets worse and can accelerate. We currently treat the disease with a range of therapies to control the symptoms, including pain, but none actually change the progression of the disease."

According to Arthritis Australia, there are more than 3.9 million people suffering with arthritis and, as the Australian population ages, this is expected to grow to 5.4 million by 2030. Unless more is done to prevent and better manage the condition the costs to the health system are expected to rise from \$5.5 billion to \$7.6 billion by 2030.

However, there is hope ...

A recent Phase 1 knee osteoarthritis trial sponsored by Sydney-based biotech company Regeneus using its patented stem cell product Progenza, has now been published in the peer-reviewed *Journal of Translational Medicine*.

Progenza cells are adult stem cells that are not

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John Martin, Regeneus

reprogrammed or genetically modified in any way. The production technology is scalable, meaning it is possible to produce millions of doses from a single donor.

Trial patients reported a significant, rapid and sustained reduction in knee pain and function. The trial also demonstrated disease modification with significant improvement in cartilage volume compared with placebo treatments.

Regenerative medicine such as Progenza, has been heralded as a new dawn in health care, capable of changing the fundamentals of disease. Approvals by the US regulator, the FDA, of new cell and gene therapies have sparked excitement for their potential significant benefits to patients.

Japan has been the country that has forged ahead. In 2014, the Japanese regulator (PMDA)

allowed regenerative medicine products that showed safety and probable efficacy, early access to the Japanese market as well as a likely government-backed 70 per cent reimbursement.

The change in law has led to a significant rise in investment in regenerative medicine R&D and corporate activity in Japan including major organisations like Fujifilm, Nikon and Hitachi.

This ongoing corporate activity has recently seen Astellas purchasing Universal Cells for \$US102.5 million, and Takeda's offer of EUR502 million for TiGenix, a European stem cell company.

"There are now very few mesenchymal stem cell players with granted IP in Japan, who have not yet formed partnerships," says Colin Lee Novick of CJ Partners, a consultancy group that specialises in regenerative medicine in Japan.

In late 2016, Regeneus partnered with Asahi Glass (AGC), part of the Mitsubishi group, a leading Japanese manufacturer of biopharmaceuticals. AGC will be the exclusive manufacturer of Progenza in Japan and through a joint venture with Regeneus are now progressing to partner the Progenza development and marketing programs in Japan.

"We're very proud of the progress we've made, without raising additional shareholders' funds since 2014," says John Martin, CEO of Regeneus.

"The climate and timing are right for a clinical and commercialisation deal in Japan for Progenza, which gives us access to further non-dilutionary capital."

Progenza is a platform technology that has application for a wide range of inflammatory diseases and Martin is confident that Regeneus will be able to license Progenza for diseases apart from osteoarthritis.

An obvious area of focus for the company is chronic pain as stem cells produce anti-inflammatories that are well known to block pain pathways.

Regeneus is collaborating with expert researchers in pain from the University of Adelaide and UNSW as part of an Australian Research Council linkage grant.

Pre-clinical results indicate that a derivative product of Progenza using only the stem cell secretions may have a similar analgesic effect to morphine, according to Martin.

"The company is excited about the potential for Progenza to address chronic pain relief without side effects associated with opioids," Martin says.

"This would be welcome relief for the millions of suffering Australians who could benefit from these leading technologies developed in Australia."

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