ADVERTISING FEATURE

Regenerative medicine

The Regeneus delegation meets with representatives of Japan's Forum for Innovative Medicine. At table (from left): Trade Minister Steve Ciobo, ambassador to Japan Richard Court, Regeneus chief executive officer John Martin.

Japan streamlines biotech approvals process

When Christopher Reeve spoke at the 1996 Paralympics, the star of four *Superman* movies was optimistic about stem cell therapy.

"He came on stage in a wheelchair and talked about the great breakthroughs in stem cell therapy that were going to help repair his spinal cord so he could walk again," recalls John Martin, the chief executive officer of clinical-stage biomedical technologies developer Regeneus.

Reeve died in 2004 from complications of the quadriplegia he had sustained in a riding accident, without seeing the therapy become a reality.

Since then however, stem cell therapy has made significant advances. Research has shifted from embryonic to adult-derived stem cells known as mesenchymal stem cells (MSCs). These MSCs can be sourced from bone marrow, placental tissue and fat.

Science now has a much clearer picture of the normal function of these adult MSCs in the body. The original excitement about stem cells centred on their capacity to differentiate into new tissue types with the potential to grow new organs.

But adult-derived MSCs act by reducing inflammation, promoting healing, and repairing and reducing scarring. Their healing and regeneration capacities mean that cell therapies and other regenerative medicines represent a new paradigm in human health.

MSCs have been described as both the paramedics and the emergency room practitioners of the body. The bioactive molecules act like first responders at an accident. First they assess the damage, then they secrete medications in the form of cytokines, growth factors and exosomes, as well as signalling actions to be taken by other cells.

More than 800 registered clinical trials are being conducted worldwide using stem cells and other regenerative medicines for a wide range of therapeutic areas including oncology, cardiovascular, musculoskeletal, dermatology and immunology and inflammation.

When the therapies were first developed, they used cells from the patient's own body, but trials indicate that donor-derived MSCs are safe and well-tolerated and will lead to easy-to-use, off-the-shelf treatments.

This new generation of stem cell products is expected to appear on the market within five years.

In April 2013, Japanese Prime Minister Shinzo Abe said in a visionary speech: "I will lead efforts to carve out a new horizon for the latest medical technologies, including regenerative medicine…"

Abe's leadership has produced results – since early 2015, Japan has become the go-to market for regenerative medicine, offering both a fast track product approval pathway and the leading market for clinical licensing and partnering.

The Japanese laws allow for conditional approval without the need for expensive and time-consuming phase 3 trials, once the regenerative medicine product has been shown to be safe, and has shown probable efficacy.

This conditional approval is limited to five to seven years, but comes with a likely 70 per cent government reimbursement.

Regeneus chief executive officer John Martin.

The EU and the US have also recognised the potential of regenerative medicines and introduced regulatory frameworks that provide avenues for accelerated approval.

Japan has an obvious interest in regenerative medicines' potential to address many of the causes of chronic diseases, which particularly affect its ageing population.

Japan's Ministry of Trade and Industry has forecast that the regenerative market will be worth $US12.7 billion within Japan and $US120 billion globally in 2030, rising to $US25 billion and $US380 billion respectively by 2050.

Regeneus' flagship product, Progenza, is an allogeneic MSC platform, meaning that it uses MSCs from fat in a healthy donor that are expanded to produce millions of doses.

It has the potential to treat a wide range of inflammatory conditions, with an initial focus on osteoarthritis of the knee.

Osteoarthritis is a major health challenge in Japan, and access to and acceptance of joint replacement surgery is limited.

Progenza passed phase 1 trials in Australia in May, meeting primary endpoints of safety and tolerability.

Progenza also showed statistically significant reduction of pain and promising signs of disease modification through the slowing and, in some cases, halting of the degradation of cartilage.

In December, Regeneus partnered with Asahi Glass (AGC), a leading Japanese manufacturer of biopharmaceuticals, in an exclusive manufacturing licence for Progenza in Japan.

As a part of the collaboration, Regeneus and AGC have formed a joint venture, Regeneus Japan Inc, to license out the clinical development and marketing rights for all clinical indications in Japan.

Japan's industry body, the Forum for Innovative Regenerative Medicine (FIRM) was set up to establish links between foreign and local businesses in the area of regenerative medicine.

In 2015, FIRM signed an MOU with Austrade to enhance collaboration between Japan and Australia.

Later this week, FIRM will sign an MOU with AusBiotech, Australia's peak biotechnology industry association, as a part of the BioJapan partnering event to be held in Yokohama in conjunction with the Regenerative Medicine Japan expo.

On the Australian side, regenerative medicine will play a key role in the upcoming AusBiotech conference in Adelaide later this month, with many Japanese FIRM members flagging their interest in the Australian industry.

John Martin is optimistic about the potential of such meetings.

"These events provide key opportunities to continue to talk to potential licensing and marketing partners."