

## asx announcement

# MESOBLAST STEM CELLS APPROVED FOR WORLD FIRST OSTEOARTHRITIS CLINICAL TRIAL

**Melbourne, Australia; 20 January 2009:** Regenerative medicine company, Mesoblast Limited (ASX:MSB; USOTC:MBLTY), today announced that it had received Australian institutional ethics approval to begin the first human trial of adult stem cell treatment for prevention of knee osteoarthritis after an acute traumatic knee injury.

The randomised, placebo-controlled, Phase 2 clinical trial design will evaluate whether Mesoblast's allogeneic, or "off-the-shelf", adult stem cell product, RepliCart, can slow or prevent the development of knee osteoarthritis after reconstruction of a ruptured Anterior Cruciate Ligament (ACL).

The trial will enrol 24 patients aged between 18 and 40 years old who have undergone recent ACL surgical reconstruction within six months of a traumatic knee injury. Patients will be randomised to receive either one of two doses of RepliCart injected into the knee joint together with hyaluronan, or hyaluronan alone. The trial's primary endpoint will be safety of the stem cell therapy at 12 months, and its secondary endpoint prevention of cartilage loss and knee osteoarthritis during this period.

In earlier preclinical trials, a single injection of Mesoblast's allogeneic stem cells into the knee joint shortly after knee surgery resulted in sustained and significant protection of joint cartilage and reduced the severity of knee osteoarthritis.

"ACL injury is very common in our young active sporting population and unfortunately the injury is associated with the early development of arthritis despite modern reconstructive procedures," said the trial's lead investigator, orthopaedic surgeon Andrew Shimmin from the Melbourne Orthopaedic Research Foundation.

"Little has changed in the prevention and treatment of arthritis over the past 50 years, so the application of Mesoblast's stem cell technology for reducing the progression of this degenerative process in the knee offers a new and exciting direction for the management of arthritis," Dr Shimmin said.

Mesoblast's Executive Director, Professor Silviu Itescu, said Mesoblast is developing a unique product for both protection and regeneration of knee cartilage in patients at risk for and with established osteoarthritis of the knee.

"Commencing this clinical trial in post-traumatic knee osteoarthritis is an important step towards accessing the huge commercial opportunity that exists today for Mesoblast in the osteoarthritis market," Professor Itescu added.

### **About knee osteoarthritis**

Osteoarthritis is the most common musculoskeletal disorder and the leading cause of joint pain and disability among the elderly. A degenerative disease characterised by the loss of cartilage, in the United States alone more than 15 million people suffer from osteoarthritis of the knee. Current therapies attempt to alleviate painful symptoms but are unable to preserve the cartilage lining the joint. Moreover, many of the currently used pharmaceutical therapies are associated with severe side effects and can even cause death. Joint replacement is often the only option for restoring function.

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### **About ruptured knee Anterior Cruciate Ligaments (ACL)**

A common severe joint injury without a fracture is a ruptured Anterior Cruciate Ligament (ACL) of the knee, which occurs in a young active patient population. Up to 70% of these patients go on to develop osteoarthritis 15 to 20 years earlier than the general population regardless of whether they have had their knees reconstructed. As there is no known treatment other than to relieve the pain, these patients face the prospect of a joint replacement at a young age. In the United States, osteoarthritis after a single acute traumatic incident comprises approximately 12% of all osteoarthritis cases with up to 300,000 new cases each year.

### **About Mesoblast**

Mesoblast Limited (ASX:MSB; USOTC:MBLTY) is committed to the development of novel treatments for orthopaedic conditions, including the rapid commercialisation of a unique adult stem cell technology aimed at the regeneration and repair of bone and cartilage. Our focus is to progress through clinical trials and international regulatory processes necessary to commercialise the technology in as short a timeframe as possible. Mesoblast has the worldwide exclusive rights for a series of patents and technologies developed over more than 10 years relating to the identification, extraction and culture of adult Mesenchymal Precursor Cells (MPCs). The Company has acquired 39% of Angioblast Systems Inc., an American company developing the platform MPC technology for the treatment of cardiac, vascular and eye diseases including repair and regeneration of blood vessels and heart muscle. Mesoblast and Angioblast are jointly funding and progressing the core technology. Mesoblast's strategy is to maximise shareholder value through both corporate partnerships and the rapid and successful completion of clinical milestones.

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