

## asx announcement

## MESOBLAST'S PROPRIETARY STEM CELLS SUCCESSFULLY REPAIR/REGENERATE DAMAGED INTERVERTEBRAL DISC CARTILAGE

- Mesoblast's proprietary adult stem cells show highly successful results for the treatment of degenerative disc disease in controlled, randomised preclinical trial
- Single injection of Mesoblast's allogeneic, or "off-the-shelf", cells reverse disc degeneration, regrow disc cartilage, and induce sustained normalisation of disc pathology, height and structure
- Mesoblast's biologic disc repair product is a non-invasive treatment approach for the number one cause of chronic low back pain
- Massive new market opportunity
- Sufficient funds in place for completion of Phase 2 clinical trials

**Melbourne, Australia**; **10 September 2009:** Australia's regenerative medicine company, Mesoblast Limited (ASX:MSB), today announced highly successful preclinical trial results of its adult stem cells in the treatment of degenerative intervertebral disc disease, the leading cause of low back pain.

A single low-dose injection of Mesoblast's allogeneic or "off-the-shelf' adult stem cells into severely damaged intervertebral discs resulted in dramatic reversal of the degenerative process, regrowth of disc cartilage, and sustained normalization of disc pathology, anatomy and function.

The results of a placebo-controlled, randomised trial of Mesoblast's cells for the treatment of degenerative disc disease in 36 sheep is being presented and highlighted at the World Congress on Osteoarthritis, OsteoArthritis Research Society International (OARSI), being held in Montreal, Canada from 10-12 September.

Six months after a single direct intra-discal injection of Mesoblast's cells, discs that were initially severely damaged and degenerated were found to have become indistinguishable from healthy non-degenerated discs in their histopathology, cartilage content, height, and structure. In contrast, severely degenerated discs which served as controls and were either not injected or were injected with hyaluronic acid, continued to demonstrate significantly reduced disc height (p<0.01), disordered disc structure (p<0.01), disrupted histopathology (p<0.01), and reduced cartilage content (p<0.05) compared with healthy non-degenerated discs over six months of follow-up. The results of disc X-Rays, Magnetic Resonance Imaging (MRIs), and histopathology were reviewed by three blinded independent experts.



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"These outstanding results indicate that we have been successful in developing a unique biologic disc repair product," Mesoblast's Executive Director, Professor Silviu Itescu, said.

"Mesoblast's cells may provide a novel therapeutic approach to reverse disc degeneration and address the number one cause of chronic low back pain," he said.

Chronic low back pain due to degenerative disc disease affects an estimated 4 million people in the United States alone. While short-term benefits may be obtained by bed rest, analgesics, physiotherapy, and steroids, many patients progress to unremitting, severe and debilitating pain due to ongoing progression of disc degeneration. For these patients, the only option is major back surgery involving artificial disc replacement or spinal fusion.

"A simple, non-invasive injection to reverse the degenerative process, and regenerate the disc back to its healthy state, would represent a major product breakthrough into an unmet market segment that is conservatively estimated at more than \$US 2 billion per year," Professor Itescu said.

"We intend to proceed rapidly with a clinical program aimed at commercial registration of our biologic disc repair product. We have sufficient funds in place to complete a Phase 2 trial, and this will progress in parallel with our other ongoing clinical programs," he added.

## **About Mesoblast**

Mesoblast Limited (ASX:MSB) 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 38.4% 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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