mesoblast
the regenerative medicine company

asx announcement

# UNITED STATES FDA CLEARS MESOBLAST PHASE 2 TRIAL TO TREAT DEGENERATIVE DISC DISEASE

**Key points:**

- Mesoblast cleared by FDA to start Phase 2 trial for chronic low back pain
- Trial will build on preclinical results showing Mesoblast's technology reversed degenerative process and regenerated intervertebral disc
- Funding in place to take disc repair product to full commercialization
- Potential multi-billion dollar market opportunity

**Melbourne, Australia; 29 June 2011**: Regenerative medicine company, Mesoblast Limited (ASX:MSB; OTC ADR: MBLTY), today announced that it has received clearance from the United States Food and Drug Administration (FDA) to begin a Phase 2 clinical trial of its proprietary adult Mesenchymal Precursor Cell (MPC) product for the treatment of degenerative disc disease. Mesoblast's biologic disc repair therapeutic is a non-invasive treatment approach for the number one cause of chronic low back pain.

The multi-center Phase 2 trial in the United States and Australia will enrol 100 patients with chronic low back pain due to lumbar disc degeneration. In 60 patients, Mesoblast's allogeneic or off-the-shelf disc regeneration MPC product will be injected into the damaged disc using one of two doses combined with hyaluronic acid carrier. Endpoints of safety and efficacy will be compared at six months against 40 control patients injected with either hyaluronic acid or saline alone.

The Phase 2 trial will build on preclinical results which showed that six months after a single low-dose injection of Mesoblast's allogeneic MPCs into severely damaged intervertebral discs there was dramatic reversal of the degenerative process, regrowth of disc cartilage, and sustained normalization of disc pathology, anatomy and function. 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.

Up to 15% of people in industrialized countries have chronic back pain lasting more than six months. 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 current option is major back surgery involving artificial disc replacement or spinal fusion.

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Chief Executive, Professor Silviu Itescu, said Mesoblast had developed a novel therapeutic approach to reverse disc degeneration and address the number one cause of chronic low back pain.

"There is a clear need for a product to reverse the degenerative process and regenerate the disc back to a healthy state. We believe our allogeneic adult stem cell product may represent a major breakthrough into this unmet market segment.

"Mesoblast has the funds in place to take this product through to full commercialization," Professor Itescu added.

**Mesoblast Limited**
Mesoblast Limited (ASX: MSB; OTC ADR: MBLTY) is a world leader in the development, manufacture, and commercialization of biologic products for the broad field of regenerative medicine. Mesoblast has the worldwide exclusive rights to a series of patents and technologies developed over more than 10 years relating to the identification, extraction, culture and uses of adult Mesenchymal Precursor Cells (MPCs). More information - www.mesoblast.com

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