

## asx announcement

## MESOBLAST COMMENCES CLINICAL PROGRAM FOR FUSION OF CERVICAL SPINE

- Phase 2 trial approved using Mesoblast's allogeneic or "off-the-shelf" stem cells for fusion of the cervical spine
- Trial seeks to translate preclinical results in which Mesoblast's cells were highly effective and safe
- Cervical spinal fusion is a major commercial market opportunity
- Limited treatment options available for patients in need of cervical fusion may provide an accelerated path to product regulatory approval

**Melbourne, Australia**; **28 April 2009**: Australian regenerative medicine company, Mesoblast Limited (ASX:MSB; PINK:MBLTY), today announced it has received approval at Melbourne's Epworth hospital to commence a Phase 2 trial of its allogeneic, or "off-the-shelf", cell therapy product for fusion of the cervical spine.

The 24-patient randomised, controlled trial will compare the safety and effectiveness of Mesoblast's product NeoFuse<sup>™</sup> against a procedure using a patient's own hipbone (autograft). In recently completed preclinical trials at Australia's Monash University, Mesoblast's allogeneic cells resulted in earlier and more robust fusion of the cervical spine than autograft, without any adverse events.

As many as 200,000 spinal fusion procedures of the cervical spine are performed annually in the United States alone for irreversible, end-stage degenerative disc disease. The limited options currently available to patients in need of cervical fusion make this a major commercial opportunity for Mesoblast and one that may represent an accelerated path to market entry.

The excellent safety profile seen in preclinical studies with Mesoblast's product NeoFuse™ was particularly important in view of the recent notification to surgeons by the United States Food and Drug Administration (US FDA) concerning life threatening complications associated with use of an alternative therapy for cervical fusion, recombinant human Bone Morphogenetic Protein (rhBMP).

Mesoblast Executive Director, Professor Silviu Itescu, said that cervical fusion represented a major, new market opportunity within a broader strategy of building a franchise for treatment of spinal diseases. These include spinal fusion of the lumbar (the lower back) and cervical (neck) vertebrae for end-stage degenerative intervertebral disc disease, and repair/regeneration of the discs for patients with earlier stage disease.



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## **About Mesoblast**

Mesoblast Limited (ASX:MSB; PINK: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 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. www.mesoblast.com

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