mesoblast
the regenerative medicine company

asx announcement

# UNITED STATES FDA CLEARS PHASE 2 TRIAL FOR CERVICAL SPINAL FUSION

## Mesoblast Builds on Cell Therapy Spinal Franchise

**Melbourne, Australia; 19 May 2010:** Australia's regenerative medicine company, Mesoblast Limited (ASX:MSB; ADR:MBLTY), today announced that it has received clearance from the United States Food and Drug Administration (FDA) to begin Phase 2 clinical trials of its "off-the-shelf" or allogeneic stem cell product NeoFuse™ for fusion of the cervical spine in the neck. As with all of Mesoblast's previous Investigational New Drug (IND) submissions, FDA clearance was obtained within the minimum 30-day period.

As many as 200,000 fusions of the cervical spine are performed each year in the United States alone, the majority for irreversible, end-stage degenerative disc disease. Mesoblast's preclinical trial results have shown that the Company's allogeneic cells generated earlier and more robust bony fusion of the cervical spine over a three-month period than either a recipient's own bone (autograft) or synthetic material, with no cell-related adverse events.

Mesoblast's Phase 2 cervical fusion clinical program will compare two doses of NeoFuse™ versus standard-of-care in 36 patients requiring bony fusion at two or more levels in the cervical spine. The FDA-cleared trial will recruit 24 patients at multiple sites in the United States, and 12 patients will be recruited at multiple sites in Australia. The trial objectives are to show the safety of the cells in this application, and whether fusion can occur faster and earlier than with standard-of-care over a six and 12-month period.

Mesoblast Chief Executive, Professor Silviu Itescu, said that cervical spinal fusion is a major commercial opportunity for Mesoblast.

"We are hopeful that the excellent results obtained with NeoFuse™ in preclinical studies will translate well in this patient population where there is a well defined, unmet clinical need for a product that can produce safe, robust and earlier fusion.

"This is an important new product within our global spinal franchise which includes our product for minimally-invasive lumbar fusion surgery, and our injectable product for regenerating intervertebral discs in patients with an earlier stage of the disease".

**About Mesoblast**
Mesoblast Limited (ASX:MSB;ADR:MBLTY) is a world leader in commercialising biologic products for the broad field of regenerative medicine. Mesoblast has the worldwide exclusive rights for 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). www.mesoblast.com

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