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First Minimally-Invasive Procedure Performed in Mesoblast's Phase 2 Stem Cell Trial for Lumbar Disc Repair

Melbourne, Australia; 22 August 2011: Regenerative medicine company, Mesoblast Limited (ASX:MSB), today announced that the first minimally-invasive lumbar disc procedure had been successfully performed in the Phase 2 clinical trial of its proprietary adult Mesenchymal Precursor Cell (MPC) product for the treatment of low back pain and degenerative disc disease. The outpatient procedure lasted less than 20 minutes, with the patient fully awake and under light sedation. The patient was shortly discharged and there were no complications.

The procedure was undertaken by leading spine surgeon, Kenneth Pettine, M.D., at the Spine Institute and Loveland Surgery Center in Colorado, a United States Spine Center of Excellence. Dr Pettine is a founder of the Spine Institute, an international leader in non-fusion surgery of the spine, and the co-inventor of Medtronic's Maverick artificial lumbar disc device.

"This marks the third renaissance in spine care," Dr Pettine said. "The first was improved diagnosis using Magnetic Resonance Imaging (MRI), the second was end-stage replacement with artificial discs, and now there is the potential widespread use of adult stem cells for disc repair and regeneration."

Up to 15 per cent of people in industrialized countries have chronic low back pain lasting more than six months. For those with progressive, severe and debilitating pain due to ongoing progression of disc degeneration, the only option is major back surgery involving artificial disc replacement or spinal fusion. Both types of surgery are associated with significant risks, and the avoidance of surgery is a major objective of new treatments for degenerative disease of the spine.

In preclinical trials, a single minimally invasive injection of Mesoblast's allogeneic MPCs into severely damaged intervertebral discs resulted in significant reversal of the degenerative process, regrowth of disc cartilage, and sustained normalization of disc pathology, anatomy and function for at least six months.

Building on these results, Mesoblast aims to show that a single minimally-invasive injection of its allogeneic or off-the-shelf disc repair MPC product can regenerate damaged discs, thereby reducing pain, improving function, and avoiding surgery. Mesoblast's Phase 2 trial, which was cleared by the United States Food and Drug Administration (FDA) last month, will enrol 100 patients with chronic low back pain due to lumbar disc degeneration in 15 centers across the United States and Australia, comparing outcomes at six months in 60 patients receiving MPC injections against 40 patients receiving control injections.

"There is a significant need for a minimally invasive biological solution to repair the degenerating disc, reduce back pain, improve function, and eliminate the need for surgery. Mesoblast's adult stem cell product could find broad use in the treatment of both early and late degenerative disc disease, and could additionally reduce spine surgery for this condition by as much as 80 per cent," Dr Pettine added.

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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). www.mesoblast.com

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