mesoblast
the regenerative medicine company

asx announcement

MESOBLAST GAINS US FDA CLEARANCE FOR PHASE 2 TRIAL IN MINIMALLY INVASIVE LUMBAR SPINAL FUSION SURGERY

Melbourne, Australia; 17 August 2009: Australian regenerative medicine company, Mesoblast Limited (ASX:MSB), today announced that it has received clearance from the United States Food and Drug Administration (US FDA) for a Phase 2 clinical trial of its allogeneic or "off-the-shelf" adult stem cells in minimally invasive lumbar spinal fusion surgery.

The 24-patient trial, based at multiple US sites, is comparing the effectiveness and safety of two low doses of Mesoblast's product, NeoFuse™, with autograft (patient's own hip bone) in minimally-invasive surgery for fusion of the lumbar spine.

Over 500,000 spinal fusion procedures are performed annually in the US alone. A minimally-invasive posterior or lateral interbody approach is the preferred procedure by surgeons in around 80 per cent of lumbar spinal fusions, with autograft remaining the FDA's gold standard for this indication, despite drawbacks such as graft pain and infection.

Preclinical trials of NeoFuse™ in minimally-invasive spinal fusion surgery showed that a lower dose than has previously been used in the lumbar spine resulted in significantly earlier bony fusion over three to six months compared with autograft, without any safety issues. If these results are confirmed in the clinical trial, this would significantly reduce cost of goods and increase product net revenues.

Because of significant safety issues, competitor biologic technologies have not been able to gain FDA approval for use in this preferred type of minimally invasive lumbar fusion surgery. The minimally invasive lumbar fusion trial will build on the safety and efficacy results generated to date in Mesoblast's first spinal fusion trial that employed a more invasive surgical approach. In that trial, unilateral use of Mesoblast's NeoFuse™ has been shown to generate safe and robust fusion over a 12-month period.

If similar results are obtained in the minimally invasive trial, this will open a major commercial opportunity for Mesoblast. After establishing safety and effectiveness during the conduct of this trial, Mesoblast plans to initiate a pivotal/Phase 3 trial to register its "off-the-shelf" product for the lucrative minimally-invasive lumbar spinal fusion surgery market.

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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