mesoblast
the regenerative medicine company

asx announcement

POSITIVE RESULTS FROM PHASE 2 LUMBAR FUSION TRIAL PRESENTED AT INTERNATIONAL INVESTOR CONFERENCE

Melbourne, Australia; 21 October 2010: Regenerative medicine company Mesoblast Limited (ASX:MSB; USOTC:MBLTY) today announced that interim results from its Phase 2 clinical trial for minimally invasive posterior lumbar spinal fusion showed that its proprietary "off-the-shelf" product NeoFuse™ was both safe and effective.

The interim trial results were presented to international investors attending the ASX Small to Mid Caps Conference in Hong Kong. The conference featured companies with market capitalizations of up to $1 billion. Mesoblast was featured as one of only two emerging leaders in the healthcare sector.

Mesoblast is currently evaluating the effectiveness and safety of NeoFuse™ for minimally invasive spinal fusion surgery of the cervical and lumbar spine in 60 patients randomized to receive either NeoFuse™ or standard therapy across two international Phase 2 trials cleared by the United States Food and Drug Administration (FDA).

The interim results from the first seventeen patients enrolled in the posterior lumbar interbody fusion trial were reviewed by the Data Safety Monitoring Board. No cell-related safety issues were seen, and in particular there was no evidence of ectopic bone formation or nerve root compression as have been reported to occur with alternative biologic therapies.

At three months of follow-up, CT scans showed that approximately 90% per cent of patients implanted with NeoFuse™ had achieved successful bone bridging. Mean pain reduction scores of more than 20% compared with baseline were achieved by both treatment groups.

These results extend earlier results from Mesoblast's pilot trial for posterolateral lumbar fusion at New York's Hospital for Special Surgery, where 60% of sites implanted with NeoFuse™ demonstrated fusion at six months compared with only 14% of sites implanted with hip autograft bone.

"We are very encouraged by these positive interim results," said Mesoblast Chief Executive Professor Silviu Itescu. "If the end-points of pain reduction and successful fusion are maintained throughout this trial, we would proceed with plans for our Phase 3/pivotal trial since these are the outcome improvements expected by a regulatory body for registration of a minimally invasive lumbar fusion product," he said.

"Moreover, the superior safety profile of NeoFuse™ could enable our product to be the only biologic therapy to be approved by the FDA for minimally invasive posterior lumbar interbody fusion, the preferred surgical procedure for chronic low back pain," Professor Itescu added.

Over 500,000 spinal fusion procedures for chronic low back and neck pain are performed annually in the United States alone, with the standard therapy being hip bone autograft obtained from a second surgical procedure. Mesoblast's NeoFuse™ would eliminate the need for a second procedure, with its associated risk of infection and chronic hip pain.

mesoblast
the regenerative medicine company

asx announcement

About Mesoblast Limited
Mesoblast Limited (ASX: MSB; ADR: MBLTY) is a world leader in commercializing 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

For further information, please contact:

Julie Meldrum
Corporate Communications Director
T: + 61 (03) 9639 6036
E: julie.meldrum@mesoblast.com