mesoblast
the regenerative medicine company

asx announcement

MESOBLAST'S NEOFUSE STEM CELL PRODUCT SHOWS POSITIVE RESULTS IN PHASE 2 LUMBAR SPINAL FUSION TRIAL
Results support progression of clinical development to Phase 3

Key points:

- Phase 2 trial results using Mesoblast's allogeneic, or "off-the-shelf", Mesenchymal Precursor Cells (MPCs) demonstrated rates of fusion success that were comparable to the gold standard bone autograft
- MPCs were well tolerated with no cell-related serious adverse events and no evidence of any ectopic bone formation
- At 12 months, fusion was achieved in 85.7% and 62.5% of patients in the low and high MPC treatment groups compared to 75% of patients who received bone autograft
- Significant improvements in low back pain scores and total disability index were seen in both MPC groups and were comparable to those receiving bone autograft
- Those receiving MPCs had 30-43% less blood loss during the surgical procedure than those receiving bone autograft ($p<0.05$)
- These results indicate that lumbar vertebral fusion using allogeneic MPCs is as effective as bone autograft
- Eliminating the need for an autograft bone harvest will avoid the risks of this procedure, including pain, infection and blood loss.

Melbourne, Australia; 11 January 2013: Regenerative medicine company Mesoblast Limited (ASX:MSB; USOTC:MBLTY) today announced that its Phase 2 clinical trial for lumbar spinal fusion had successfully met its safety and efficacy endpoints.

The results suggest that Mesoblast's NeoFuse product comprising allogeneic Mesenchymal Precursor Cells (MPCs) is as effective for interbody lumbar fusion as the gold standard, bone autograft, without the need for a second surgical procedure and its attendant morbidity risks. These results support the progression of clinical development of NeoFuse to a Phase 3 trial in interbody lumbar fusion.

The results were highlighted during a presentation to the 31st annual JP Morgan Healthcare Conference in San Francisco by Mesoblast Chief Executive Professor Silviu Itescu.

Twenty four (24) patients were enrolled and randomized over 5 sites in the United States with 8 patients in each treatment arm – bone autograft standard of care (Control), 25 million MPCs (25M), and 75 million MPCs (75M). Patients underwent the surgical procedure, one or two level fusions using a posterior approach to the spine, and were evaluated for safety and efficacy. The median follow-up times for the three treatment groups were 23.9, 20.7, and 22.9 months for the bone autograft, 25M, and 75M groups, respectively.

MPCs were well tolerated with no cell-related serious adverse events and no ectopic bone formation at all. Notably, MPC treated groups had 30-43% lower mean estimated blood loss during surgery compared to the autograft treatment group ($p<0.05$ for the 25M group).

At 12 months, fusion was achieved in 85.7% of patients in the 25M treatment group compared to 62.5% in the 75M and 75% in the control patient groups.

Overall, patients from all three treatment groups had a clinically significant and comparable decrease in low back and leg pain, assessed on the Visual Analogue Scale and functional improvement, assessed by the Oswestry Disability Index questionnaire.

Dr Randall Dryer, an orthopedic surgeon with the Central Texas Spine Institute and an investigator in Mesoblast's study, said: "For patients whose spinal discs have degenerated too extensively for repair, bony fusion of adjacent vertebra is the primary option to eliminate chronic and debilitating pain.

"Other than autograft, there is no approved product for posterior spinal fusion, a surgical approach which accounts for 62% of all lumbar fusion procedures. There is a critical unmet need for new technologies to achieve fusion that are safe, effective, and that eliminate the need for bone autograft.

"Based upon my experience in the Phase 2 study, Mesoblast's cells may provide a significant and valuable option to achieve fusion in patients with severe spinal disc degeneration and these results warrant progressing to a Phase 3 study," Dr Dryer added.

According to Millennium Research Group, in the United States there were approximately 380,000 lumbar spinal fusion procedures performed in 2012. They estimate the overall worldwide market for bone graft substitutes to be nearly $1.6 billion dollars in 2012 with the majority of bone graft revenues, approximately 70%, coming from spinal fusion procedures.

Mesoblast plans to initiate a Phase 3 trial for interbody lumbar fusion later this year, with patients to be enrolled across multiple sites in the United States, Europe and Australia.

Mesoblast Limited
Mesoblast Limited is a world leader in the development, manufacture, and commercialization of biologic products for the broad field of regenerative medicine. Mesoblast's patented Mesenchymal Precursor Cell (MPC) technology is being developed for a broad range of major clinical diseases, including inflammatory and immunologic conditions, diabetes and its complications, orthopedic spine conditions, and cardiovascular disorders. www.mesoblast.com

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