asx announcement

mesoblast
the regenerative medicine company

MESOBLAST REPORTS POSITIVE INTERIM RESULTS IN PHASE 2 TRIAL OF PROPRIETARY ADULT STEM CELLS FOR INTERVERTEBRAL DISC REPAIR

Key Points

- Mesoblast's Phase 2 trial of allogeneic, or "off-the-shelf", Mesenchymal Precursor Cells (MPCs) injected into damaged intervertebral discs has now completed six-month follow-up for all 100 patients enrolled
- A pre-specified interim analysis of Phase 2 trial results was performed when 50% of patients completed six months of follow-up. This analysis demonstrated that a single low-dose MPC injection resulted in significantly greater reduction in low back pain and improvement in function than was seen in patients receiving the hyaluronic acid carrier alone, with no cell-related safety issues
- In the interim analysis, 71% of patients who received a low dose MPC injection met the pre-specified treatment success criteria at 6 months compared with only 20% and 30% of the patients in the two control arms who received hyaluronic acid and saline
- Full trial results expected in Q3 2013
- Confirmation of interim results would support progression to Phase 3 for MPC treatment of chronic discogenic low back pain.

Melbourne, Australia; 22 April 2013: Regenerative medicine company Mesoblast Limited (ASX:MSB; USOTC:MBLTY) today announced that all 100 patients in its Phase 2 clinical trial of its proprietary Mesenchymal Precursor Cells (MPCs) for intervertebral disc repair had completed six months of follow-up, the endpoint at which data will be evaluated for progression to Phase 3.

Additionally, Mesoblast announced that it had completed the pre-specified interim analysis which was performed when 50% of the patients had completed their six month follow-up visits. The analysis showed a positive outcome, with a single low-dose injection of MPCs causing a significantly greater reduction in low back pain, significantly greater improvement in function, and significantly greater treatment success compared with patients who received hyaluronic acid carrier alone, with no cell-related serious adverse events.

Over 6 million patients in the United States alone are currently dealing with chronic back pain that has persisted for at least three months. The CDC's National Center for Health Statistics reported in 2010 that low back pain was the leading cause of pain, affecting 28% of American adults. The United States lifetime prevalence of low back pain is estimated to be at least 60-84%. Total costs of low back pain are estimated to be between $100 billion and $200 billion annually, two thirds of which are due to decreased wages and productivity.

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In Mesoblast's Phase 2 clinical trial, 100 patients were enrolled across 13 sites in the United States and Australia. Patients were randomized to receive direct intra-disc injection of saline (n= 20), hyaluronic acid (HA, n=20), 6 million MPCs in hyaluronic acid carrier (6M, n=30) or 18 million MPCs in hyaluronic acid carrier (18M, n=30). Patients underwent the outpatient injection procedure for a single painful degenerated lumbar level and were evaluated for safety and efficacy at 30 days, 3 months and 6 months. Patients will continue to be followed for a total of 36 months to evaluate long-term treatment effects.

The pre-specified interim analysis was conducted when 50% of the enrolled patients had completed 6 months follow up. At 6 months, patients in all four treatment arms demonstrated substantial improvement in pain and function compared to baseline. Patients injected with 6M MPCs + HA demonstrated significantly greater improvement in back pain and function relative to baseline when compared with patients receiving HA alone (mean reduction in back pain 69% vs 38%, p=0.013, and mean improvement in function 51% vs 19%, p=0.038). Similar trends were seen comparing 6M MPC-treated patients against saline-treated patients. MRI status of disc morphology remained unchanged at 6 months relative to baseline in all groups.

Overall treatment success was defined as the pre-specified composite requiring a patient to meet all of the following criteria: clinically significant levels of improvement in back pain and function at 6 months compared to baseline, maintenance or improvement in neurological status from baseline, maintenance of disc morphology compared to baseline as evaluated by MRI, and no serious adverse event or secondary intervention. In the interim analysis, 71% of patients treated with 6M MPC+HA were determined to be a treatment success compared with 20% in the HA alone group (p=0.036) and 30% in the saline injected group (p=0.095). Additionally, the 6M MPC group showed significantly higher overall treatment success rates than the group receiving 18M MPCs, due to both lower efficacy and higher incidence of adverse events with the higher dose.

"We are pleased that the interim results of this important study have identified a low MPC dose that appears to be safe and effective for inducing sustained improvement in low back pain and function," said Mesoblast Chief Executive Professor Silviu Itescu.

The complete results of the Phase 2 trial will be presented during the third quarter 2013. If the full results are consistent with the interim results, Mesoblast plans to commence a Phase 3 trial of a single MPC dose injected into damaged intervertebral discs to treat chronic low back pain.

It is important to note that while interim results are often indicative, they should not be taken as conclusive of the final trial results. The Company does not at present have the full analyzed data from all 100 patients in the trial, and there is no guarantee the full trial results will match the interim data.

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

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