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mesoblast
the regenerative medicine company

MESOBLAST REPORTS POSITIVE 24 MONTH RESULTS IN PHASE 2 TRIAL FOR CHRONIC LOW BACK PAIN AND INITIATION OF PHASE 3 PROGRAM AT JP MORGAN HEALTHCARE CONFERENCE

New York, USA, and Melbourne, Australia; 15 January 2015: Mesoblast Limited (ASX: MSB, USOTC: MBLTY) today presented positive 24 month results from its Phase 2 program for chronic low back pain at the JP Morgan 33rd Annual Healthcare Conference being held in San Francisco.

Additionally, Mesoblast announced that its Phase 3 program for this indication has been initiated. Mesoblast presented anticipated timelines for this Phase 3 program and noted that enrollment completion is expected in mid-2016, an interim analysis is expected in mid-2016 and top-line data are expected in mid-2017.

In the randomized, placebo-controlled Phase 2 trial of 100 patients with chronic low back pain due to degenerative disc disease, a single injection of Mesoblast's allogeneic investigational mesenchymal precursor cell (MPC) product, MPC-06-ID, was well tolerated and was shown to result in substantial improvement in pain and function for at least 24 months.

Highlights of the clinical results were:

- A single injection of 6 million MPCs induced substantial and sustained pain relief over 24 months. At 12 and 24 months, 46% and 48% of MPC-06-ID-treated patients achieved minimal or no residual pain (VAS ≤20) compared with 13% and 13% of saline treated patients, p=0.042 and 0.093, respectively.

- In patients who received a single injection of 6 or 18 million MPCs, 44% and 42%, respectively, achieved the target composite endpoint of treatment success at both 6 and 12 months (50% reduction in pain, 15 point improvement in function and no further treatment intervention), compared with 13% of saline controls (p=0.006 and p=0.020).

- In patients who received 6 million MPCs and achieved the target composite endpoint of treatment success at both 6 and 12 months, 86% (11 of 13) maintained treatment success at 24 months (32% vs 11% saline controls, p=0.001).

Mesoblast Chief Executive Silviu Itescu said: "Our product candidate, MPC-06-ID, has shown the potential to provide durable improvement in pain and function for the many patients who suffer with chronic low back pain due to degenerative disc disease. We are excited to begin the Phase 3 program so that we may potentially provide a therapeutic modality for this major unmet need."

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The objective of the Phase 3 clinical program will be to confirm the positive outcomes from the Company's Phase 2 clinical trial. The primary endpoint will seek to confirm the treatment success seen in Phase 2 for MPC-06-ID against a control injection of saline.

Chronic Discogenic Low Back Pain (CDLBP)
Mesoblast's investigational product candidate MPC-06-ID is being developed to target the population of patients suffering from moderate to severe chronic low back pain due to moderately degenerated discs. The target patient population has exhausted conservative treatment options, may have failed epidural steroid injections to alleviate pain and has no treatment option other than invasive and costly surgical interventions. Over four million patients in the United States alone suffer from CDLBP. Total costs of low back pain are estimated to be between US$100 billion and US$200 billion annually with two thirds of attributed to patients' decreased wages and productivity.

Mesoblast Limited
Mesoblast Limited (ASX: MSB; USOTC: MBLTY) is a global leader in regenerative medicine. The Company has leveraged its proprietary technology platform, which is based on specialized cells known as mesenchymal lineage adult stem cells (MLCs), to establish a broad portfolio of late stage product candidates. Mesoblast's allogeneic or 'off-the-shelf' cell product candidates target significantly advanced stages of diseases where there are highly unmet medical needs, including orthopedic disorders, cardiovascular disorders, immunologic/inflammatory disorders and oncology /hematology conditions. Lead product candidates under investigation include MPC-06-ID for chronic discogenic low back pain, MPC-150-IM for chronic congestive heart failure, in partnership with Teva Pharmaceutical Industries Ltd., MSC-100-IV for acute graft versus host disease (aGVHD) and MPC-300-IV for biologic refractory rheumatoid arthritis and diabetic nephropathy.

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