

MESOBLAST REPORTS POSITIVE TYPE 2 DIABETES TRIAL RESULTS

Melbourne, Australia and New York, USA; 4 December 2013: Regenerative medicine company Mesoblast Limited (ASX:MSB; USOTC:MBLTY) today announced top-line results from the Phase 2 trial of its proprietary Mesenchymal Precursor Cells (MPCs) in subjects with type 2 diabetes. The results of the trial support the safety and tolerability of a single intravenous infusion of MPCs in type 2 diabetes. Additionally, there was an improvement in glycemic control as evidenced by reduction in hemoglobin A1c (HbA1c).

The Phase 2 randomized, single-blind, placebo-controlled, dose escalation trial was conducted across 18 sites in the United States. The trial evaluated the effects of a single intravenous infusion of 0.3, 1.0 or 2.0 million MPCs/kg or placebo over 12 weeks in 61 patients with a mean diabetes duration of 10 years.

Key positive findings were:

- The MPCs were safe and well tolerated with no treatment-related adverse events, meeting the trial's primary endpoint.
- Following a single intravenous MPC infusion, overall HbA1c levels were reduced over the 12-week study period when compared to placebo.
- The highest dose showed the greatest overall reduction in HbA1c, with a peak decrease of 0.4% at 8 weeks compared with placebo ($p < 0.05$), and a decrease of 0.3% at 12 weeks.
- In the less well-controlled subjects, as defined by a baseline HbA1c $\geq 8.0\%$, a 0.6% decrease in HbA1c was seen at 8 weeks in the high dose cohort compared with placebo.
- In those with baseline HbA1c $< 8\%$, a target of HbA1c $< 7\%$ at week 12 was achieved in 63% (5/8) of high-dose treated subjects compared with 0/7 placebo controls ($p < 0.05$).

Mesoblast Chief Executive Silviu Itescu said: "We are very pleased and encouraged by these top-line results. In this phase 2 trial, a single injection of Mesoblast's MPCs was well tolerated and showed evidence of improved glycemic control in type 2 diabetes, a chronic inflammatory disease affecting multiple organs.

"This is an important first step in developing an MPC-based immunomodulatory therapy for the treatment of type 2 diabetes and its complications."

According to the World Health Organization, there are more than 347 million people worldwide with diabetes and the number is likely to more than double by 2030 without intervention. In the United States alone, according to the American Diabetes Association there were 18.8 million people suffering from type 2 diabetes in 2011. According to the United States Food and Drug Administration Guidance for Industry 2008, HbA1c is the primary endpoint of choice for glycemic control in subjects with type 2 diabetes.

About Mesoblast

Mesoblast Limited (ASX: MSB; USOTC: MBLTY) is a world leader in the development of biologic products for the broad field of regenerative medicine. The Company's proprietary technologies include its Mesenchymal Precursor Cell and culture-expanded Mesenchymal Stem Cell technology platforms, Dental Pulp Stem Cells and expanded Hematopoietic Stem Cells. Mesoblast's allogeneic or 'off-the-shelf' regenerative medicine products are being developed for the treatment of conditions with significant unmet medical needs. The lead product candidates use its mesenchymal lineage cells in four major and distinct areas - systemic inflammatory conditions, cardiovascular diseases, orthopedic diseases of the spine, and oncology conditions. www.mesoblast.com

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