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the regenerative medicine company

TYPE 2 DIABETES TRIAL RESULTS PRESENTED BY STUDY INVESTIGATORS AT AMERICAN DIABETES ASSOCIATION ANNUAL MEETING

New York, USA; and Melbourne, Australia; 19 June 2014: Results from the Phase 2 trial of Mesoblast's proprietary adult stem cells in type 2 diabetes patients have been presented by Jay S. Skyler, M.D., on behalf of study investigators, at the Scientific Sessions of the 74th American Diabetes Association annual meeting held June 13-17 in San Francisco, USA. The annual meeting is the largest diabetes conference in the world, bringing together nearly 18,000 participants, including more than 14,000 clinicians and researchers from 118 countries.

Type 2 diabetes and its complications are considered to have an underlying immunological component associated with excessive pro-inflammatory cytokines, and the immunomodulatory properties of Mesoblast's Mesenchymal Precursor Cells (MPCs) provided the rationale for conducting the study.

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 who were inadequately controlled on metformin alone or with one other glucose-lowering agent. Mean diabetes duration was 10 years.

The following were highlighted as key findings from the study:

- During the 12-week study period there were no safety issues and the cell infusions were well tolerated (with a maximal dose of 246 million cells).
- There was a dose-dependent improvement in glycemic control as evidenced by a decrease at all timepoints after week 1 in hemoglobin A1c (HbA1c) in MPC-treated patients compared with an increase in HbA1c in placebo treated subjects.
- A significant reduction in HbA1c was seen after 8 weeks in the 2 M/kg MPC group compared to placebo ($p<0.05$) which was sustained through 12 weeks.
- The reduction in HbA1c was most pronounced in subjects with baseline HbA1c ≥ 8% (i.e. those patients with relatively poorer glucose control).
- Fasting insulin levels were reduced in the 1M and 2M/kg groups compared to placebo ($P<0.05$).
- Reduced levels of inflammatory cytokines TNF-alpha and IL-6 were observed at 12 weeks in MPC groups compared to placebo.

The study investigators concluded there was sufficient evidence to support further evaluation into the use of MPCs in type 2 diabetes and its complications, and to explore further the effects of MPCs on disease mechanisms.

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Mesoblast Chief Executive Silviu Itescu said: "We are very pleased with these results which are consistent with an immunomodulatory mechanism by which our MPCs may have glucose-lowering effects in patients with type 2 diabetes. We are evaluating whether similar effects may be seen with the use of MPCs in the treatment of kidney disease and other complications of type 2 diabetes."

Mesoblast Limited

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 highly purified, immunoselected Stro-1/Stro-3 positive Mesenchymal Precursor Cells (MPCs), culture-expanded Mesenchymal Stem Cells (MSCs), Dental Pulp Stem Cells (DPSCs), and expanded Hematopoietic Stem Cells (HSCs). Mesoblast's protein technologies are based on factors derived from its proprietary cellular platforms, including Stromal Derived Factor-1 (SDF-1). Mesoblast's allogeneic or 'off-the-shelf' regenerative medicine products are being developed for the treatment of conditions with significant unmet medical needs. Product development focus is in four major and distinct areas - systemic diseases with an underlying inflammatory and immunologic etiology; cardiac and vascular diseases; orthopedic diseases of the spine; and improving outcomes of bone marrow transplantation associated with oncology or genetic conditions. www.mesoblast.com

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