asx announcement

mesoblast
the regenerative medicine company

DIABETIC NEPHROPATHY TRIAL RESULTS SELECTED FOR LATE-BREAKING PRESENTATION AT AMERICAN DIABETES ASSOCIATION ANNUAL MEETING

New York; USA; and Melbourne, Australia; 18 May 2015: Mesoblast Limited (ASX:MSB; USOTC: MBLTY) today announced that Phase 2 trial results of its lead product candidate for the treatment of diabetic nephropathy have been selected for presentation at the late-breaking scientific sessions of the 75th American Diabetes Association (ADA) Scientific Sessions being held from June 5-9 in Boston, MA. The annual meeting is the largest diabetes meeting in the world, bringing together approximately 14,000 participants, including clinicians and researchers from 124 countries.

As many as 40-50% of people with type 2 diabetes develop progressive decline in renal function due to nephropathy (or kidney disease), despite use of existing therapies. These patients have a high rate of progression to dialysis and death due to cardiovascular events. Abnormal chronic inflammation and microvascular dysfunction which persist in the diabetic kidney over many years are thought to be important causal factors in the development of progressive diabetic nephropathy.

Mesoblast is developing its allogeneic mesenchymal precursor cell (MPC) product candidate, MPC-300-IV, for intravenous delivery in the treatment of specific conditions caused by excessive inflammation and endothelial dysfunction, including biologic-refractory rheumatoid arthritis and diabetic nephropathy. By down-regulating pro-inflammatory cytokines produced by monocytes and T cells, MPCs may counteract the destructive inflammatory processes and vascular dysfunction implicated in these diseases.

To establish an MPC dose range that is safe and effective for use in diabetic patients, Mesoblast initially performed a randomized, placebo-controlled, dose-escalating Phase 2 trial in patients with type 2 diabetes, insulin resistance and poor glycemic control, but without kidney disease. In that trial, a single infusion of allogeneic MPCs resulted in a dose-dependent improvement in hemoglobin A1c levels (HbA1c), the recommended primary endpoint by the FDA for glycemic control in diabetic patients. The greatest decrease relative to placebo was seen at eight weeks following a single dose of 2 million MPCs/kg or a total dose of at least 150 million MPCs ($p<0.05$).

Using results from this dose-ranging study as a guide, Mesoblast conducted a double-blind, randomized, placebo-controlled, dose-escalating Phase 2 trial in 30 patients with type 2 diabetes and moderate to severe renal impairment, stage 3b-4 chronic kidney disease (www.clinicaltrials.gov/ct2/show/NCT01843387). The objectives of the trial were to evaluate safety and tolerability of a single infusion of 150 or 300 million MPCs in patients with diabetic nephropathy, and to explore potential efficacy signals in terms of renal function and biomarkers of inflammation at 12 weeks, with ongoing follow-up for an additional 48 week period. Initial results for this trial will be presented by the trial's principal investigator at the upcoming ADA meeting.

Diabetic Nephropathy

Diabetic nephropathy is the single leading cause of end-stage kidney disease, accounting for nearly half of all end-stage kidney disease cases in the United States. There were an estimated 1.96 million cases of severe diabetic nephropathy in 2013. The current standard of care (renin-angiotensin system inhibition with angiotensin converting enzyme inhibitors or angiotensin II receptor blockers) only slows the rate of progression to kidney failure by 16-25%, leaving a large residual risk for end-stage kidney disease. For patients with end-stage kidney disease, the only treatment option is renal replacement (dialysis or kidney transplantation) which incurs high medical costs and substantial disruptions to a normal lifestyle. Due to a severe shortage of kidneys, in 2012 approximately 92,000 persons in the United States died while on the transplant list. For those on dialysis, the mortality rate is high with an approximately 40% fatality rate within two years.

Mesoblast Limited
ABN 68 109 431 870
www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia
T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA
T +1 212 880 2060
F +1 212 880 2061

Asia
20 Biopolis Way
#05-01 Centros
Biopreneur 3
SINGAPORE 138668
T +65 6570 0635
F +65 6570 0176

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, 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 cardiovascular conditions, orthopedic disorders, immunologic/inflammatory disorders and oncology/hematology conditions. The lead therapeutic product candidates under investigation include MPC-150-IM for chronic congestive heart failure; MPC-06-ID for chronic discogenic low back pain; MSC-100-IV for acute graft versus host disease, and MPC-300-IV for biologic refractory rheumatoid arthritis, and diabetic nephropathy.

For further information, please contact:
Julie Meldrum
Global Head of Corporate Communications
Mesoblast Limited
T: +61 (0) 3 9639 6036
E: julie.meldrum@mesoblast.com