

PHASE 2 TRIAL RESULTS OF MESOBLAST'S CELL THERAPY IN DIABETIC KIDNEY DISEASE PUBLISHED

New York; USA; and Melbourne, Australia; October 6, 2016: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today announced that results from the randomized, placebo-controlled Phase 2 trial of its proprietary allogeneic Mesenchymal Precursor Cell (MPC) product candidate, MPC-300-IV, in patients with diabetic kidney disease have been published in the current issue of the peer-reviewed journal *EBioMedicine*.

The paper, entitled '*Allogeneic Mesenchymal Precursor Cells (MPC) in Diabetic Nephropathy: A Randomized, Placebo Controlled, Dose Escalation Study*', concluded that a single intravenous infusion of MPC-300-IV was well tolerated and had positive effects on renal function at the 12-week primary endpoint in a Phase 2 trial in adult patients with type 2 diabetic nephropathy. The study was conducted by researchers at the University of Melbourne, Epworth Medical Centre and Monash Medical Centre in Australia.

The Phase 2, double-blind, randomized, placebo-controlled, dose-escalating trial evaluated MPC-300-IV in patients with type 2 diabetes and moderate to severe renal impairment, stage 3b-4 chronic kidney disease (CKD), who were already on a stable regimen of the standard of care therapy for diabetic nephropathy (renin-angiotensin system inhibition with angiotensin converting enzyme inhibitors or angiotensin II receptor blockers). A total of 30 patients were randomized to receive a single infusion of 150 million MPCs, 300 million MPCs, or saline control on top of maximal therapy.

The objectives of the trial were to evaluate safety and to explore potential efficacy signals of MPC-300-IV treatment on renal function. The primary efficacy endpoint of decline or change in glomerular filtration rate (GFR) was in line with the 2012 joint workshop held by the United States Food and Drug Administration and the National Kidney Foundation, which recommended that time to 30%-40% decline in GFR is an acceptable primary endpoint for evaluating potential benefits of new therapies for this patient population.

Key trial results were:

- Safety profile for MPC-300-IV treatment was similar to placebo, with no treatment-related adverse events.
- Efficacy testing showed that patients receiving a single MPC infusion at either dose had improved renal function relative to placebo, as defined by preservation or improvement in GFR at 12 weeks.
- The rate of decline in estimated GFR at 12 weeks was significantly reduced in the group receiving a single dose of 150 million MPCs relative to the placebo group (p=0.05).
- There was a trend toward more pronounced treatment effects relative to placebo in the pre-specified subgroup of patients with GFR>30 ml/min/1.73m² at baseline (p=0.07).

Dr David Packham, Associate Professor in the Department of Medicine at the University of Melbourne, Director of the Melbourne Renal Research Group, and lead author on the publication said: "The efficacy signal observed with respect to preservation or improvement in GFR is exciting, especially given that this trial was not powered to show statistical significance. Patients receiving a single infusion of MPC-300-IV showed no evidence of developing an immune response to the administered cells, suggesting that repeat administration is feasible and may in the longer term be able to halt or even reverse progressive chronic kidney disease. I hope that this very promising investigational therapy will be advanced to rigorous Phase 3 clinical trials to test this hypothesis as soon as possible."

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About 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 and over 40% of new patients entering dialysis treatment. There were almost 2 million cases of moderate to severe diabetic nephropathy in 2013.

Diabetic nephropathy occurs even when glucose levels are well controlled, and is thought to be due to chronic infiltration of the kidneys by inflammatory monocytes which secrete pro-inflammatory cytokines resulting in endothelial dysfunction and fibrosis.

Staging of CKD is based on absolute levels of GFR, and GFR decline is on the path of progression to kidney failure (stage 5, GFR < 15ml/min/1.73m²). 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.

About Mesoblast's Product Candidate MPC-300-IV and Potential Mechanisms of Action

Mesoblast is developing MPC-300-IV for the treatment of specific conditions caused by excessive inflammation and endothelial dysfunction, including biologic-refractory rheumatoid arthritis and diabetic nephropathy.

MPCs produce immunomodulatory biomolecules such as prostaglandin E2 (PGE2) and indoleamine 2,3-dioxygenase (IDO), in response to activation by pro-inflammatory cytokines such as tumor necrosis factor-alpha (TNF-alpha), interleukin-1, -6, or -17 (IL-1, IL-6 or IL-17). This results in modulation of multiple immune pathways, including polarizing pro-inflammatory M1 monocytes to anti-inflammatory M2 monocytes, and switching activated Th1 and Th17 T cells to anti-inflammatory Th2 cells and FOXP3 T regulatory cells.

About Mesoblast

Mesoblast Limited (ASX:MSB; Nasdaq:MESO) is a global leader in developing innovative cell-based medicines. 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, 'off-the-shelf' cell product candidates target advanced stages of diseases with high, unmet medical needs including cardiovascular diseases, immune-mediated and inflammatory disorders, orthopedic disorders, and oncologic/hematologic conditions.

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Forward-Looking Statements

This press release includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. You should read this press release together with our risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, and accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

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