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CONGESTIVE HEART FAILURE PHASE 2 TRIAL RESULTS PUBLISHED IN CIRCULATION RESEARCH

New York; USA; and Melbourne, Australia; 15 July 2015: Mesoblast Limited (ASX:MSB; USOTC: MBLTY) today announced that Phase 2 trial results of its cell therapy product candidate for the treatment of congestive heart failure (CHF) have been published in the latest edition of *Circulation Research.* The results were published as an "online first" article ahead of full print in this peer-reviewed, high-impact journal of the American Heart Association.

Patients with advanced heart failure have a poor long-term prognosis and few therapeutic options. Mesoblast's proprietary Mesenchymal Precursor Cells (MPCs) may offer a promising alternative because of their ability to induce heart muscle repair, stimulate new blood vessel growth, decrease cell death and reduce scar formation.

In the article, entitled '*A Phase II Dose-Escalation Study of Allogeneic Mesenchymal Precursor Cells in Patients With Ischemic or Non-Ischemic Heart Failure'*, the authors concluded that high-dose allogeneic MPC treatment may reduce heart failure-related major adverse cardiovascular events (HF-MACE) and provide beneficial effects on adverse left ventricular remodelling.

Key results of the 60-patient, placebo-controlled trial were:

Primary Endpoint of Safety

- Transendocardial injections of allogeneic MPCs into the hearts of patients with either ischemic or non-ischemic heart failure due to left ventricular systolic dysfunction were feasible and safe, with a similar incidence of adverse events across all control and treatment groups.
- Treatment of patients with allogeneic MPCs was not associated with any clinically significant immune response.

Secondary Efficacy Endpoints

- Patients treated with the highest dose, MPC 150M, showed the greatest improvement in left ventricular remodeling compared to controls; this was evidenced by significant reductions in Left Ventricular End Systolic Volume (LVESV), p=0.015, and Left Ventricular End Diastolic Volume (LVEDV), p=0.02, at month 6 post treatment relative to controls.
- Parallel improvements in both LVESV and LVEDV in the MPC-treated patients may have accounted for the observed non-significant changes in ejection fraction.
- Patients treated with the highest dose, MPC 150M, showed the greatest improvement in functional exercise capacity compared to controls (6MTW: p=0.062) at month 12 post treatment.

Major Adverse Cardiovascular Events (MACE)

- In a post-hoc analysis after all patients had completed 36 months of follow up, treatment with MPC 150M was shown to be associated with a significantly lower incidence of HF-MACE events compared to the control group (0% vs 33% HF-MACE by Kaplan-Meier, p=0.026 by log-rank).

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

Lead author and investigator Dr Emerson C. Perin, Director, Research in Cardiovascular Medicine and Medical Director of the Stem Cell Center at the Texas Heart Institute, said: "The findings from this trial are very encouraging and suggest that a high-dose of Mesoblast's allogeneic cell-based therapy may decrease major clinical events associated with progressive heart failure for at least three years, including repeated hospitalizations or death.

"These effects appear to be due to the ability of these cells to positively impact on adverse cardiac remodeling associated with chronic heart failure. If these results are confirmed in the ongoing Phase 3 trial currently recruiting at our institution and elsewhere, this new therapy has the potential to change the paradigm for the management of patients with advanced heart failure and a high risk of hospitalization and death," Dr Perin added.

The randomized, placebo-controlled Phase 3 trial using Mesoblast's high-dose MPC 150M is being conducted by Mesoblast's development and commercial partner, Teva Pharmaceutical Industries Ltd., and is actively enrolling patients across multiple clinical sites in North America.

The primary efficacy endpoint for the Phase 3 trial is a time-to-first-event analysis of HF-MACE, the same efficacy endpoint achieved in the Phase 2 trial by the group receiving MPC 150M.

Congestive Heart Failure
CHF is a chronic condition characterized by an enlarged heart and insufficient blood flow to the organs and extremities of the body. The condition, which affects 2% of the adult population of the United States, is progressive and can be caused by many factors that put an excess demand on the heart muscle such as high blood pressure, faulty valves, infections or congenital heart problems. CHF prevalence is expected to grow 46% by 2030, affecting more than 8 million Americans.

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