

PHASE 3 HEART FAILURE TRIAL SIZE TO BE SUBSTANTIALLY REDUCED FOLLOWING FDA DISCUSSIONS

New York, USA; and Melbourne, Australia; 11 January 2016: Mesoblast Limited (ASX:MSB; Nasdaq:MESO) today announced that the size of the ongoing Phase 3 trial in chronic heart failure (CHF) of its proprietary cell-based medicine MPC-150-IM is planned to be substantially reduced. This follows communications last month between Mesoblast's development and commercial partner, Teva Pharmaceutical Industries Ltd., and the United States Food and Drug Administration (FDA).

Mesoblast Chief Executive Silviu Itescu said: "The reduction in the size of the Phase 3 trial may significantly shorten the time to trial completion."

The ongoing Phase 3 program is planned to be optimized as follows:

- The FDA has agreed to a reduction in the current Phase 3 trial size from 1,165 to approximately 600 patients due to a proposed change in the primary endpoint
- The revised primary endpoint will be a comparison of recurrent heart failure-related major adverse cardiovascular events (HF-MACE) between patients treated with MPC-150-IM and controls
- The proposed use of recurrent HF-MACE as a primary endpoint in the Phase 3 trial is based on the fact that a single injection of MPC-150-IM successfully prevented recurrent HF-MACE over three years in the Phase 2 trial
- A second confirmatory study will be conducted in parallel in an identical patient population of approximately 600 subjects using the same primary endpoint.

In the completed Phase 2 trial, patients treated with MPC-150-IM had no HF-MACE over 36 months of follow-up, compared with 11 HF-MACE events in the control group ($p < 0.001$, log rank test). In patients with advanced heart failure as defined by baseline Left Ventricular Systolic Volume $> 100\text{ml}$, who closely resemble the patients being recruited in the Phase 3 trial, 71% of controls had at least one HF-MACE event vs 0 of those who received a single injection of MPC-150-IM ($p < 0.001$).

"Patients with advanced heart failure continue to represent among the largest unmet medical needs, where existing therapies are inadequate and the economic burden is the greatest. The current Phase 3 trial targets this patient population, continues to recruit well across North America, and is now expanding to Europe," Dr Itescu added.

Chronic Heart Failure

CHF is characterized by an enlarged heart and insufficient blood flow to the organs and extremities of the body. The condition 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. The American Heart Association reports 5.7 million adults in the United States with diagnosed CHF, or about 2% of the adult population, with 870,000 new cases diagnosed each year. New York Heart Association Class II / III CHF patients with low ejection fraction continue to be at high risk of repeated hospitalizations and mortality, despite standard of care pharmacological treatments. CHF prevalence is expected to increase by 46% by 2030, affecting more than 8 million Americans. The estimated annualized cost for CHF is approximately \$32 billion, and is projected to grow to \$77 billion by 2030.

Mesoblast

Mesoblast Limited (ASX: MSB; Nasdaq: MESO) is a global leader in 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 where there are highly unmet medical needs, including cardiovascular conditions, orthopedic disorders, immunologic and inflammatory disorders and oncology/hematology conditions.

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

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