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mesoblast
the regenerative medicine company

PHASE 3 TRIAL OF MESOBLAST'S CELL THERAPY IN CHRONIC HEART FAILURE COMPLETES RECRUITMENT

New York, USA; and Melbourne, Australia; January 7, 2019: Mesoblast Limited (ASX:MSB; Nasdaq:MESO), world leader in development and commercialization of allogeneic (off-the-shelf) cellular medicines, today announced that it has completed patient recruitment in the events-driven Phase 3 trial of its product candidate Revascor (MPC-150-IM) for advanced chronic heart failure.

Mesoblast Chief Executive Dr Silviu Itescu stated: "Completion of recruitment in this Phase 3 trial, the largest cell therapy trial for heart failure, is a key milestone for Mesoblast and has been achieved on plan. This is a substantial step forward in our objective to bring an effective therapy to countless patients with progressive heart failure, and a tremendous commercial opportunity for Mesoblast."

The Phase 3 trial is evaluating whether Revascor reduces recurrent non-fatal heart failure-related major adverse cardiac events (HF-MACE), and prevents or delays terminal cardiac events (TCEs), defined as cardiovascular death, heart transplant or placement of an artificial device, over at least 12 months. In a previous Phase 2 trial, a single dose of Revascor prevented any TCEs or hospitalization events over three years in a similar patient cohort.

The Phase 3 trial has enrolled approximately 570 patients across 55 centers in North America. This enrollment target was guided by the observed reduction in event rate in the Phase 2 trial and reinforced by the successful outcome of a pre-specified futility analysis of the Phase 3 trial's primary endpoint performed after the first 270 patients were enrolled.

The trial's co-principal investigator, Dr Emerson Perin, Medical Director of Texas Heart Institute and Director of its Stem Cell Center, said: "We are very pleased to have completed recruitment in this important trial of a cellular therapy for advanced heart failure patients who have few alternatives. If the Phase 3 trial results confirm the earlier Phase 2 data, where we saw improvements in patient function as well as reductions in hospitalizations and deaths, this important technology will transform cardiovascular care and would provide a powerful new treatment for advanced heart failure."

There are over 8 million patients with heart failure in the United States alone, with 15-20% refractory to all existing medicines and progressing to advanced heart failure[1] (New York Heart Association Class III or IV). These patients represent a major unmet medical need due to their high rates of HF-MACE events and mortality.

Dr Itescu added: "Over the past 12 months, Mesoblast has completed recruitment in all three of its Phase 3 trials, for acute graft versus host disease, chronic low back pain, and now chronic heart failure."

About Mesoblast

Mesoblast Limited (ASX:MSB; Nasdaq:MESO) has leveraged its proprietary technology platform to establish a broad portfolio of late-stage allogeneic (off-the-shelf) product candidates with three product candidates in Phase 3 trials – acute graft versus host disease, chronic heart failure and chronic low back pain due to degenerative disc disease. Through a proprietary process, Mesoblast selects rare mesenchymal lineage precursor and stem cells from the bone marrow of healthy adults and creates master cell banks, which can be industrially expanded to produce thousands of doses from each donor that meet stringent release criteria, have lot to lot consistency, and can be used off-the-shelf without the need for tissue matching. Mesoblast has facilities in Melbourne, New York, Singapore and Texas and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). www.mesoblast.com

1. AHA's 2017 Heart Disease and Stroke Statistics Update

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