mesoblast
the regenerative medicine company

asx announcement

HEART MUSCLE FUNCTION IMPROVED SIGNIFICANTLY AFTER SINGLE, LOWEST-DOSE INJECTION OF "OFF-THE-SHELF" STEM CELLS IN PATIENTS WITH HEART FAILURE

Three-month results show safety and efficacy

- Single injection into damaged heart muscle of the lowest dose of Revascor™, a proprietary allogeneic, or "off-the-shelf", adult stem cell therapy significantly improved heart function over three months in first group of patients with congestive heart failure
- Heart function significantly greater at three months in patients receiving Revascor™ compared with placebo-controlled, randomised controls
- Greatest improvement seen in patients with most severe heart failure
- No cell-related safety concerns
- Multiple United States hospitals actively recruiting second group of patients to be treated with next higher dose of cells

Melbourne, Australia; 14 May 2009: Australia's regenerative medicine company, Mesoblast Limited (ASX:MSB; PINK: MBLTY), today announced positive three-month interim efficacy results from the first 20 patients enrolled in the Phase 2 heart failure trial of the proprietary allogeneic, or "off-the-shelf", adult stem cell product Revascor™.

Three months after receiving a single injection into damaged heart muscle of the lowest dose of Revascor™, patients with moderate-severe congestive heart failure demonstrated significantly improved heart muscle function.

The randomised, placebo-controlled Phase 2 trial is being run at multiple centres in the United States by Mesoblast's United States-based associated company Angioblast Systems Inc. The trial aims to compare one of three increasing doses of Revascor™ against standard of care in up to 60 patients suffering from moderate-severe congestive heart failure, defined as a baseline ejection fraction (EF) 40% or lower by echocardiogram.

On the basis of the positive interim efficacy results and the excellent safety profile seen to date in the first group of patients receiving the lowest dose of Revascor™, the second group of patients set to receive the next higher dose is currently in active recruitment.

In the first 20-patient cohort, 15 were randomised to receive the lowest dose of Revascor™ and 5 were randomised to the control arm. While control patients with baseline EF 40 or below demonstrated an 11% mean *decrease* in EF over the first 3 months (mean EF values decreased from 31 to 27), patients with baseline EF 40 or below who received a single injection into damaged heart muscle of the lowest dose of Revascor™ showed a 37% mean *increase* in EF over this period (mean EF increased from 28 to 37, $p=0.017$). The 10-point mean difference in absolute EF at three months between cell-treated and control patients was significant ($p<0.05$).

Patients with the most severe and advanced heart failure, defined as a baseline EF < 30 (9 patients treated with Revascor™), had an even greater improvement in heart function, with mean *increase* in EF over three months of 50% ($p=0.02$).

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Executive Director, Professor Silviu Itescu, said he was very encouraged by the three-month interim efficacy results seen after a single injection of the lowest dose of the proprietary allogeneic stem cells into damaged heart muscle.

“We eagerly await the six month results to see whether these effects are sustained or even further augmented,” Professor Itescu said. “If the clinical trial continues to parallel our pre-clinical results, we anticipate even better outcomes in the next group of patients receiving a higher dose of Revascor™.”

International heart failure expert Professor Henry Krum, Director of Monash University’s Centre of Cardiovascular Research & Education in Therapeutics, said, “These initial results are very exciting. Equally as important is the lack of any safety concerns to date, meaning that for the first time we could potentially have a safe and effective off-the-shelf cell therapy product which could change the treatment paradigm for patients with chronic heart failure.”

Congestive heart failure remains a leading cause of hospital admissions, morbidity and mortality in the Western world. There are currently more than five million people in the United States suffering from congestive heart failure, with over 550,000 new cases annually. Despite major strides in prevention and treatment, heart failure is responsible for about 1.1 million hospitalisations in the US alone each year, and some 300,000 deaths. Total direct costs in the US exceed $US 33 billion annually.

Revascor™, a trademark of Angioblast Systems Inc, is an allogeneic cell therapy product being developed to reverse congestive heart failure by rebuilding both blood vessels and heart muscle.

About Mesoblast
Mesoblast Limited (ASX:MSB; PINK:MBLTY) is committed to the development of novel treatments for orthopaedic conditions, including the rapid commercialisation of a unique adult stem cell technology aimed at the regeneration and repair of bone and cartilage. Our focus is to progress through clinical trials and international regulatory processes necessary to commercialise the technology in as short a timeframe as possible. Mesoblast has the worldwide exclusive rights for a series of patents and technologies developed over more than 10 years relating to the identification, extraction and culture of adult Mesenchymal Precursor Cells (MPCs). The Company has acquired 38.4% of Angioblast Systems Inc., an American company developing the platform MPC technology for the treatment of cardiac, vascular and eye diseases including repair and regeneration of blood vessels and heart muscle. Mesoblast and Angioblast are jointly funding and progressing the core technology. Mesoblast's strategy is to maximise shareholder value through both corporate partnerships and the rapid and successful completion of clinical milestones. www.mesoblast.com

For further information, please contact:
Julie Meldrum
Corporate Communications Director
Mesoblast Limited
T: + 61 (03) 9639 6036
E: julie.meldrum@mesoblast.com