



## asx announcement

### **FIRST GROUP OF HEART FAILURE PATIENTS TREATED WITH “OFF-THE-SHELF” ADULT STEM CELLS SUCCESSFULLY PASS KEY SAFETY MILESTONE**

**Melbourne, Australia; 25 February 2009;** Australia's regenerative medicine company, Mesoblast Limited (ASX:MSB; PINK:MBLTY), today announced successful achievement of the key safety milestone in the first low-dose cohort of patients treated with Revascor™, the proprietary allogeneic, or “off-the-shelf”, universal adult stem cell product for congestive heart failure.

Safety data from all 20 congestive heart failure patients enrolled in the multi-centre Phase 2 clinical trial by Mesoblast's United States-based sister company Angioblast Systems Inc. were reviewed by the trial's Data Safety and Monitoring Board (DSMB), as mandated by the Food and Drug Administration (FDA). No cell-related adverse events occurred in any patient during the 30-day follow-up period and the review was positive.

As a result, the DSMB has allowed the company to move forward with recruiting the second 20-patient cohort of patients with congestive heart failure. This group will receive a higher dose of cells.

The placebo-controlled trial of Angioblast's Revascor™ cell therapy will randomise up to 60 patients suffering from congestive heart failure to three 20-patient cohorts receiving either a progressively increasing dose of the company's allogeneic adult stem cells or standard of care.

The cells are implanted into the damaged heart muscle using the NOGA MyoStar catheter technology system provided through a collaborative agreement with Johnson & Johnson companies, Biologics Delivery Systems and Cordis Cardiology.

The outcomes in each patient group following injection of progressively increasing doses of cells will be compared against standard-of-care in terms of both safety and effectiveness at halting or reversing congestive heart failure. The company will provide interim efficacy results for each dose cohort as they become available.

Executive Director Professor Silviu Itescu said he was very encouraged by the safety profile of Revascor™ to date.

“Patient recruitment has proceeded in a very rapid manner, reflecting both the excellent safety profile of our cells and the ease of delivery of an allogeneic cell therapy in this very ill patient population in serious need of effective new treatments. We will now move forward with the next dose in our trial,” he said.

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.

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.



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### **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 39% 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.

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