mesoblast
the regenerative medicine company

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PROPRIETARY TECHNOLOGY IN WORLD-FIRST ALLOGENEIC STEM CELL TRIAL FOR TREATMENT OF END-STAGE HEART FAILURE IN PATIENTS SUPPORTED BY MECHANICAL HEART ASSIST DEVICES

- **Multi-centre Phase 2 trial initiated using proprietary "off-the-shelf" stem cells in patients with end-stage heart failure who are supported temporarily by a mechanical heart assist device and waiting for a heart transplant**
- **Trial funded by multi-million dollar grant from the United States National Institutes of Health**
- **Aim is to evaluate whether proprietary cells can improve heart muscle function, potentially enabling removal of mechanical device and eliminating need for transplant**
- **Short primary endpoint of 60-90 days**

Melbourne, Australia; 5 August 2009: Australian regenerative medicine company, Mesoblast Limited (ASX: MSB), today announced that its United States-based associate company Angioblast Systems Inc. has initiated a Phase 2 clinical trial to evaluate the safety and effectiveness of the company's proprietary "off-the-shelf" adult stem cell product Revascor™ for improving heart muscle function in patients with the most severe, or class IV, end-stage form of heart failure.

The clinical trial will be performed across multiple medical centres in the United States and will involve 80 patients who are waiting to receive a heart transplant from an appropriate donor and are being kept alive temporarily by a Left Ventricular Assist Device (LVAD) manufactured by medical device company Thoratec.

The trial will evaluate whether injections into the damaged heart of either of two increasing doses of Revascor™ improve heart muscle function compared with control injections over a 60-90 day period, potentially enabling the patient to have the LVAD removed and to no longer require a heart transplant.

The clinical trial is being conducted under an Investigational New Drug (IND) submission that has been cleared by the United States Food and Drug Administration (FDA), and is funded by a multi-million dollar grant awarded by the United States National Institutes of Health (NIH).

Very few treatment modalities are available for patients with end-stage heart failure who have a very high early mortality. Heart transplantation is not an option for the vast majority of these patients because of the great shortage in organ donors. An LVAD can temporarily keep end-stage heart failure patients alive while they are waiting for an appropriate organ donor, but cannot improve function of the damaged heart to a level where a transplant is no longer necessary. If Revascor™ can improve heart muscle function in this patient population, it could result in a new therapy for large numbers of class IV heart failure patients without the need for a heart transplant.

This clinical trial will complement Angioblast's existing Phase 2 program in class II-IV heart failure patients with less severe loss of heart muscle function who do not require either an LVAD or a heart transplant. Recently announced interim results from that ongoing Phase 2 trial have shown that patients with the most severe loss of heart muscle function have demonstrated the greatest recovery over a three-month period after receiving a single, lowest-dose of Revascor™. These initial results now form the basis for testing Revascor™ in those class IV patients with the worst decline in heart muscle function, requiring LVAD support.

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Executive Director, Professor Silviu Itescu, said: "We are very pleased that our proprietary stem cell technology has been selected for evaluation in this ground-breaking trial funded by the NIH."

“This is a patient group with a very high mortality for whom there are few alternatives. If our technology can improve heart muscle function to a level where the LVAD support can potentially be removed without the need for a heart transplant, we will have changed the treatment paradigm for this most severe group of heart failure patients," he added.

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 exceed $US33 billion annually.

Revascor™ 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) 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.

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