

## asx announcement

### **Phase 2 Clinical Trial Results Show That Revascor™ Increases Blood Supply to Damaged Heart Muscle**

Mesoblast expands target indications to new vascular diseases including chronic refractory angina

#### Key Points:

- Trial results show Mesoblast's proprietary "off-the-shelf" adult stem cell product Revascor™ increases blood supply to damaged heart muscle
- By contrast, control patients showed no improvement in perfusion
- Improved blood flow results in long-term reduction in major adverse cardiac events
- Based on these results, Mesoblast will target major new markets for vascular disorders
- Chronic angina will be the third Revascor™ product indication, in addition to congestive heart failure and acute myocardial infarction (heart attack), establishing a multi-pronged cardiovascular franchise
- Phase 2b trials for chronic angina and heart attack to commence shortly in Europe, United States and Australia

**Melbourne, Australia; 9 June 2011:** Results from Mesoblast's cardiovascular clinical trials were featured at the Goldman Sachs 32nd Annual Global Healthcare Conference in California today.

Mesoblast Chief Executive, Professor Silviu Itescu, presented results showing that the company's lead cardiovascular product Revascor™ improves blood flow in ischemic heart muscle and reduces long term vascular-related complications. On the basis of these results, Mesoblast will now proceed with Phase 2b trials of Revascor™ for the treatment of vascular conditions including chronic refractory angina and acute myocardial infarction (heart attacks).

In a subset analysis of the ongoing 60-patient United States trial of Revascor™ for congestive heart failure, 22 patients were found to have reduced myocardial blood flow at baseline by SPECT perfusion scan, indicating the presence of ischemic heart muscle. Of these, 17 were randomized to receive treatment with Revascor™ while 5 were randomized as controls. Six months after treatment with a single injection of Revascor™ there was significant improvement in blood flow to the ischemic heart muscle, with 51% reduction in myocardial ischemia (p=0.01). In contrast, no change in blood flow to the ischemic heart muscle was seen at six months in the controls.



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These improvements in blood flow and in myocardial ischemia in patients treated with Revascor™ were accompanied by a 75% reduction in the risk of Major Adverse Cardiac Events (MACE) over a mean follow-up period of 21 months compared with controls with myocardial ischemia and no change in blood flow. MACE are defined as a clinical composite of death due to cardiac causes, non-fatal heart attacks, or revascularization episodes.

"These positive results open up major new market opportunities for our lead cardiovascular product Revascor™," Professor Itescu told the global investor forum.

"By improving blood flow to ischemic heart muscle Revascor™ may be an effective treatment for a broader range of vascular heart conditions and their life-threatening consequences.

"We are particularly excited about the prospect that Revascor™ could be highly effective for patients with chronic refractory angina who do not have other therapeutic options and are so debilitated by pain that their physical activity is either markedly restricted or non-existent.

"Indeed, in an earlier pilot trial in Australia where we treated such patients with a single injection of an autologous, or patient specific, version of Revascor™ our proprietary stem cells were highly effective for reduction in angina symptoms and use of anti-angina medications for as long as six months."

"Given these exciting clinical results, we intend to file an Investigational New Drug (IND) application with the United States Food and Drug Administration (FDA) to commence a Phase 2b trial of Revascor™ in approximately 150 patients with chronic refractory angina by the end of this year."

Professor Itescu also told the conference that Mesoblast has just submitted a Clinical Trial Application to European regulatory authorities to commence a Phase 2b trial of 225 patients with heart attacks. The company plans to extend this trial to the United States and Australia. The aims of the trial are to see if a single injection of Revascor™ at the time of a major heart attack can prevent the complication of heart failure, reduce infarct size, and lower the frequency of MACE.

Expanding the use of Revascor™ into new vascular indications such as chronic refractory angina and acute myocardial infarction represents multi-billion dollar annual market opportunities in addition to the congestive heart failure market. In the United States alone there are over one million patients with refractory angina not amenable to cardiovascular therapies, and over 200,000 new patients annually. Additionally, over a million new heart attack patients are treated in the United States alone.

Revascor™ is being jointly developed by Mesoblast and its strategic alliance partner Cephalon as a simple off-the-shelf therapy for direct injection into heart muscle or for use in conjunction with angioplasty and stent procedures.

To access a live audio webcast of Professor Itescu's presentation, please use this link: [http://cc.talkpoint.com/gold006/060711a\\_lr/?entity=67\\_IKXHJB0](http://cc.talkpoint.com/gold006/060711a_lr/?entity=67_IKXHJB0).



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### **About Mesoblast Limited**

Mesoblast Limited (ASX: MSB; OTC ADR: MBLTY) is a world leader in the development, manufacture, and commercialization of biologic products for the broad field of regenerative medicine. Mesoblast has the worldwide exclusive rights to a series of patents and technologies developed over more than 10 years relating to the identification, extraction, culture and uses of adult Mesenchymal Precursor Cells (MPCs). More information - [www.mesoblast.com](http://www.mesoblast.com).

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