



angioblast
systems

HEART FUNCTION IMPROVES IN STEM CELL TRIALS

Key points

- Patients treated with adult stem cells show substantial and sustained improvement in heart function
- Recently completed large animal studies show a mean of 50% greater heart function for animals treated with our stem cells compared with untreated animals
- Clinical and preclinical trial data for FDA submission in 4th quarter 2006.

New York, United States; 19 September 2006: Angioblast Systems, Inc. today announced positive clinical and preclinical trial data associated with its adult stem cell technology in the treatment of heart disease.

“Interim results from our heart disease clinical trial at the John Hunter Hospital have shown that heart function has improved in each of the patients treated so far,” Angioblast Founder and Chief Scientific Adviser, Professor Silviu Itescu, said.

“Importantly, our clinical trial experience has been further supported by results from a number of large animal studies we have just completed using allogeneic stem cells, or cells obtained from unrelated donors, to improve heart function after a heart attack.

“In these studies, heart function in stem cell treated animals was significantly superior to control groups that did not receive stem cells, confirming the safety and effectiveness of our frozen, pre-cultured Allogeneic stem cells,” Professor Itescu said.

Clinical Trial Using Patients' Own Cells Shows Improvement In Heart Function

Angioblast Systems in conjunction with Australia-based sister company Mesoblast Limited, are conducting a Pilot Clinical Trial at the John Hunter Hospital in New South Wales.

The Trial is focused upon the treatment of up to 10 patients suffering from severe coronary artery disease and heart muscle damage. Cells used in the treatment are autologous, or the patients' own cells, which have been selected and cultured using the company's proprietary technology.

The primary endpoint of the Trial is to show safety of the company's Standard Operating Procedures (SOPs) in a clinical setting. Data are also being collated to evaluate the effects of the treatment on heart function.



Initial results now demonstrate the therapy has been highly effective in the first three patients who have been treated.

In up to six months of follow-up after the patients' cells were implanted into their damaged heart muscle, each patient had demonstrated improvement in global heart function of 20-60% relative to baseline, as determined by serial echocardiograms.

Principal Investigator at the John Hunter Hospital, interventional cardiologist Dr Suku Thambar, said he was extremely encouraged by the results to date.

"This degree of improvement in heart function in these very ill patients is extremely encouraging, and we look forward to completing the trial and reporting on the outcomes of all the patients in due course," Dr Thambar said.

Preclinical Trial Using 'Off-The-Shelf' Cells Deliver Improvement In Heart Function

The company has now completed a number of large animal studies for the collation of data to be provided to the United States Food and Drug Administration (FDA) in support of Angioblast's Investigational New Drug applications.

The studies focused upon the treatment of post myocardial infarct or heart attack animals using the company's adult stem cell technology. In particular, the studies have looked at efficacy associated with repairing damaged heart muscle and improving heart function using cells from a non-related or allogeneic donor. These cells had been expanded and frozen post GMP compliant manufacturing, in effect, an 'off-the-shelf' stem cell product.

All studies have been undertaken by specialist organizations and results have been independently reviewed.

In one completed study at the University of Pennsylvania, 36 sheep underwent coronary artery occlusion and were treated with either a placebo or the company's stem cells obtained from an unrelated donor.

On the trial's completion at two months, the 25 animals which were treated with the Allogeneic stem cells demonstrated a 50% greater mean global heart function than the 11 controls, as determined by serial echocardiograms. Importantly, pathology studies have not shown evidence of allergic reaction, rejection, or abnormal tissue formation.

"These are major steps forward in completing the company's commitment to finalizing its IND submissions during the 4th quarter 2006 and in proving the company's primary business model to develop an off-the-shelf cell therapy product for improving heart function," Professor Itescu added.



About Angioblast Systems, Inc.

Angioblast Systems, Inc. is an American company developing the platform MPC technology for the treatment of cardiovascular diseases, including repair and regeneration of blood vessels and heart muscle.

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