



angioblast
systems

UNITED STATES FDA CLEARS PHASE 2 TRIAL FOR CONGESTIVE HEART FAILURE Major New Market Opportunity

Key Points:

- FDA clears Phase 2 clinical trial for congestive heart failure
- Third IND submission cleared for platform stem cell technology
- Multiple centers in US to participate
- Major milestone hit on time and within budget

New York, 5 June 2008: Angioblast Systems Inc. today announced that the United States Food and Drug Administration (US FDA) had cleared an Investigational New Drug (IND) submission by its US-based sister company, Angioblast Systems Inc., to commence a Phase 2 trial of the stem cell platform technology for treating patients with congestive heart failure.

The trial will enroll 60 patients with heart failure at multiple major centres across the US. Fifteen patients will serve as controls and 45 will receive one of three doses of the company's patented allogeneic (donor unrelated or "off-the-shelf") adult stem cells. Study endpoints will include measurement of heart muscle function and improvement in heart failure symptoms at six and 12 months.

In this trial, the company's patented allogeneic cells will be injected into damaged heart muscle by cardiac catheter, in a similar way to the company's ongoing Phase 2 trial in patients with heart attacks. The cardiac catheter technology for this trial will be provided through an ongoing collaboration with the Johnson & Johnson companies Cordis Corporation and Biosense Webster.

In parallel with this Phase 2 trial, Angioblast will continue its ongoing preclinical collaboration with Abbott, a major global broad-based health care company, to jointly develop a heart failure product. The company expects that the results of both the Phase 2 clinical trial and its preclinical collaboration will support the subsequent filing of a pivotal, Phase 2b/3 clinical trial.

In a recent Australian pilot trial, injection of the company's autologous cells (patients' own) resulted in improvement in heart muscle function and reduced symptoms of both heart failure and severe angina. Additionally, the company's allogeneic cells have been shown to improve heart muscle function and reverse established heart failure in preclinical trials.

"Obtaining rapid FDA clearance to begin a Phase 2 trial of our allogeneic cells in patients with heart failure confirms the robustness of the clinical and preclinical results of the platform adult stem cell technology", said company founder Professor Silviu Itescu.

"Treatment of heart failure is a major unmet clinical need and a huge commercial opportunity for us. If our initial clinical and preclinical results are mirrored in this Phase 2 trial, we will have a unique and highly effective product for this massive, and growing, market," Professor Itescu added.

About Congestive Heart Failure

Heart failure is a leading cause of death in the developed world, and is estimated to affect over 11 million people worldwide. In the United States alone, nearly 5 million patients suffer from heart failure, making this condition a major cause of total hospitalisations, chronic disability, and mortality. Each year in the United States 550,000 new cases are diagnosed and some 300,000 patients die because of the progressive condition.

Heart failure results from the progressive deterioration of the pumping function of the heart, leading to its inability to pump sufficient blood to the body's tissues, organs and limbs. The majority of heart failure patients have underlying cardiovascular disorders that are often the precursors of their condition. The most common of these are atherosclerosis, myocardial infarction, hypertension, cardiomyopathy and arrhythmia.

About Mesoblast

Mesoblast Limited (ASX:MSB; USOTC:MBLTY) is committed to 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 that have been developed over more than 10 years and which relate to the identification, extraction and culture of adult Mesenchymal Precursor Cells (MPCs). The Company has also acquired 39% of Angioblast Systems Inc., an American company developing the platform MPC technology for the treatment of cardiovascular 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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