mesoblast
the regenerative medicine company

asx announcement

Positive Results from Phase 2 Trial of Mesoblast's Adult Stem Cell Therapy Presented at the American Heart Association Annual Meeting

- Revascor™, Mesoblast's proprietary Mesenchymal Precursor Cell (MPC) product for cardiovascular diseases, was safe and well-tolerated at all doses, with no clinically relevant immune responses to donor cells
- Revascor™ therapy significantly reduced cardiac mortality and major adverse cardiac events (MACE) in patients with congestive heart failure over a mean follow-up of 22 months
- Highest dose of Revascor™ completely prevented any episodes of heart failure hospitalization over 18 months of follow-up
- Clinical improvement was associated with evidence of remodeling (reduction in heart volumes) and improvement in functional capacity (increased walking distance), which are key parameters in congestive heart failure
- Revascor™ anticipated to progress to Phase 3 trial in first half of 2012

Orlando, United States; 14 November and Melbourne, Australia; 15 November 2011 – Regenerative medicine company Mesoblast Limited (ASX:MSB; OTC ADR:MBLTY) today announced positive Phase 2 heart failure trial results of its allogeneic, or off-the-shelf, adult stem cell product Revascor™ after all patients had completed a minimum follow-up of 12 months, and a mean follow-up of 22 months. The Phase 2 trial results in 60 patients were presented at the American Heart Association annual meeting in Orlando, Florida, by the trial's independent principal investigator Dr Emerson C. Perin, Director of Research in Cardiovascular Medicine and Medical Director, Stem Cell Center, Texas Heart Institute in Houston.

MPC treatment pooled across all doses in 45 patients resulted in significant reduction in cardiac mortality compared with 15 controls, and at the highest dose resulted in complete prevention of heart failure hospitalization events. Mesoblast expects that these outcomes will be central to the primary endpoint of a Revascor™ Phase 3 trial for product regulatory approval by the United States Food and Drug Administration (FDA).

The randomized, placebo-controlled Phase 2 trial compared the safety and efficacy of three doses of Revascor™ on top of maximal approved therapies versus maximal therapies alone in the patients, all with moderate-to-severe congestive heart failure (CHF) defined by New York Heart Association (NYHA) class II or III status and ejection fractions below 40%. The trial enrolled both ischemic and non-ischemic heart failure patients. Heart failure patients with this degree of severity are known to have a high cardiac mortality over a 12-24 month period despite being on maximal approved drug and device therapies.

Treatment with MPCs was well-tolerated, with 13% of patients developing transient or persistent anti-donor antibodies which were without clinical consequence. Over a 22-month mean follow-up period, only 1/45 (2%) patients who received a single injection of Revascor™ died of cardiac causes compared with 3/15 (20%) controls (p=0.02). In addition, MPC treatment significantly delayed the time to a first Major Adverse Cardiac Event, MACE, a composite of cardiac death, heart attack or revascularization procedures (p=0.036), and reduced the overall risk for MACE by 78% (p=0.011).

Over a mean follow-up of 18 months, 0/15 patients who received the highest dose of MPC (150M) had been hospitalized for heart failure or had died. In contrast, 3/15 (20%) controls and 6/30 (20%) patients who received low (25M) or mid (75M) doses of MPC had either been hospitalized with heart failure or had died. This clinical improvement associated with the 150M dose was accompanied by evidence of cardiac remodelling (reduction in left ventricular end systolic volumes compared with controls at 6 months, p=0.015) and improved functional capacity (gain of 52.6 meters over 6 minutes' walk compared with controls at 12 months, p=0.06).

After 12 months, 40% of all treated patients had reverted to class I NYHA status compared with 14% of all controls, and this effect remained when patients were matched for the presence of class II status at baseline. The group who received the 25M MPC dose showed a significant 8.9 point improvement in ejection fraction over controls at 3 months (p=0.008), with a sustained but less pronounced effect over 12 months. In contrast, the group who received 150M MPC did not show improved ejection fraction, suggesting that the positive effects of this dose on clinical outcomes, remodeling, and functional capacity may be due to other mechanisms such as anti-fibrosis.

"These clinical findings are the first using any cell therapy in heart failure patients to show a concordant positive effect on clinical outcomes, cardiac remodelling, and functional capacity, the three key parameters in congestive heart failure. Together, they indicate that a single 150 million dose of Revascor™ may significantly reduce both heart failure hospitalizations and death in these very sick patients who have such a poor prognosis despite maximal existing therapies," Dr Perin said.

"Based on their defined product characterization, batch to batch consistency, immediate availability, and lack of clinically relevant immunogenicity, MPCs appear to be an ideal cell type to provide a new level of patient care in congestive heart failure. We look forward to progressing the Revascor™ clinical program into Phase 3," Dr Perin added.

Revascor™ is being jointly developed by Mesoblast and its strategic alliance partner, Teva Pharmaceutical Industries Ltd.

Teva's Corporate Vice President Global Branded Products, Kevin Buchi, said: "These independently-reviewed results serve to reinforce Teva's commitment to its strategic investment in Mesoblast's adult stem cell technology and to our continued support for the clinical development of Revascor."

Mesoblast Chief Executive, Professor Silviu Itescu, said, "Together with our partners at Teva, we are deeply committed to bringing to market an effective cell therapy product to reduce recurrent hospitalization episodes and risk of death in patients with progressive heart failure. The exciting results presented at the American Heart Association meeting reinforce the strength of our technology and emphasize the need to maintain a rapid development path in order to make this product available for the many patients suffering with heart failure."

About Congestive Heart Failure
More than 6 million people in the United States suffer from congestive heart failure (CHF) with an additional 670,000 new cases diagnosed each year. Heart failure is the number one cause of mortality and hospitalization in the Western world. It is characterized by an enlarged heart and insufficient blood flow to the extremities of the body. The condition develops over time and can be caused by many factors that put an excess demand on the heart muscle, including high blood pressure, incompetent valves, infections of the heart muscle or valves, or congenital heart problems. Although patients are initially treated with drug therapy, the only method of treating end-stage disease currently is a heart transplant or mechanical assist device. Only around 3,000 heart transplants are performed annually in the United States.

About Revascor™
Revascor™, Mesoblast's proprietary Mesenchymal Precursor Cell (MPC) product for cardiovascular diseases, is being developed using the Company's adult stem cell technology platform. Revascor™ is being jointly developed by Mesoblast and its strategic alliance partner Teva Pharmaceutical Industries as an "off-the-shelf" therapy for the treatment of cardiovascular diseases.

About Mesoblast
Mesoblast Limited (ASX: MSB) is a world leader in commercialising biologic products for the broad field of regenerative medicine. Mesoblast has the worldwide exclusive rights for 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). www.mesoblast.com

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