mesoblast
the regenerative medicine company

asx announcement

INTERIM RESULTS FROM MESOBLAST'S PHASE 2 HEART FAILURE TRIAL SHOWS "OFF-THE- SHELF" PROPRIETARY ADULT STEM CELL PRODUCT REVASCOR™ REDUCES CARDIAC EVENTS, MORTALITY, AND HOSPITALIZATION

Frazer, Pa. and Melbourne, Australia, 10 January 2011: Cephalon, Inc. (Nasdaq: CEPH) and Mesoblast Limited (ASX: MSB; OTC ADR: MBLTY) today announced positive interim results from Mesoblast's ongoing multi-center Phase 2 trial of its "off-the-shelf" proprietary adult stem cell product Revascor™ for patients with congestive heart failure. Patients who received a single injection of Revascor™ into damaged heart muscle have had less cardiac events, deaths, and hospitalizations during the follow-up period to date than control patients.

Cephalon and Mesoblast have entered into a strategic alliance to develop and commercialize Mesoblast's Mesenchymal Precursor Cell (MPC) therapeutics for hematopoietic stem cell transplantation in cancer patients, as well as degenerative conditions of the central nervous and cardiovascular systems, including congestive heart failure.

Mesoblast is evaluating the safety and efficacy of Revascor™ in a randomized, placebo-controlled Phase 2 trial in 60 patients with moderate-severe congestive heart failure. A single injection of Revascor™ at one of three progressively increasing doses has been administered to 45 patients randomized to receive cell therapy in addition to standard-of-care, while 15 control patients have been concomitantly randomized to receive standard-of-care alone. The trial will be completed when all available patients have been followed-up for 12 months.

A scheduled interim analysis of safety and of time-dependent hard efficacy endpoints was performed when the last of the 60 enrolled patients had completed six months of follow-up in December 2010. At this time point, the 45 patients who received Revascor™ had been followed for a mean of 18.5 months/patient and the 15 controls had been followed for a mean of 18 months/patient.

There have been no cell-related adverse events in any of the 45 patients treated with Revascor™, demonstrating that all three doses of the cell therapy product are safe over both the short and medium term.

Analyses of time-dependent hard efficacy endpoints showed that a single injection of Revascor™ significantly reduced the number of patients who developed any severe adverse cardiac events over the follow-up period from 93.3% in the control group to 44.4% in the treated patients ($p=0.001$). Revascor™ also significantly reduced the number of patients who developed any major adverse cardiac events (MACE, defined as the composite of cardiac death, heart attack, or coronary revascularization procedures) from 40% to 6.7% ($p=0.005$). A single injection of Revascor™ reduced the overall monthly event rate of a MACE by 84% compared with controls ($p=0.01$), and every dose tested demonstrated a similar protective effect. Death from cardiac causes was reduced from 13.3% to 0% over this period ($p=0.059$) and the overall monthly rate of cardiac-related hospitalizations was reduced by 48% ($p=0.07$).

Mesoblast CEO Professor Silviu Itescu said: "We are very pleased with these interim results that show for the first time that our proprietary technology can impact both quality of life and survival. If these long-term beneficial outcomes from a single dose of our adult stem cells are sustained they will translate into significant improvements to the quality of life and longevity of patients who are struggling with debilitating congestive heart failure".

Cephalon CEO J. Kevin Buchi said: "These results underscore Cephalon's strong belief in the value of our strategic investment in Mesoblast's innovative adult stem cell technology platform. We shall now look to progress clinical development of Revascor™ for the treatment of congestive heart failure towards a Phase 3/pivotal trial."

Mesoblast plans to present the complete trial results at an appropriate cardiology conference.

About Heart Failure
Congestive heart failure remains a leading cause of hospital admissions, morbidity and mortality in the Western world. The American Heart Association and the National Heart, Lung, and Blood Institute have estimated that cardiovascular disease and stroke cost the United States at least US$448.5 billion annually, and the burden continues to grow as the population ages. In the United States alone, congestive heart failure has an annual incidence of 670,000 patients, a prevalence of 6.2 million patients, and causes over 1.1. million hospitalizations and 300,000 deaths per year. Heart failure affects around 10 million in Europe and as many as 20 million worldwide.

About Revascor
Revascor™ is an allogeneic cell therapy product being developed to reverse congestive heart failure by rebuilding both blood vessels and heart muscle. Revascor™ is delivered to damaged areas of the heart by a minimally invasive cardiac catheterization procedure performed under local anaesthesia while the patient is awake. Patients undergoing the procedure are usually released from the hospital within 24 hours.

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

About Cephalon, Inc.
Cephalon is a global biopharmaceutical company dedicated to discovering, developing and bringing to market medications to improve the quality of life of individuals around the world. Since its inception in 1987, Cephalon has brought first-in-class and best-in-class medicines to patients in several therapeutic areas. Cephalon has the distinction of being one of the world's fastest-growing biopharmaceutical companies, now among the Fortune 1000 and a member of the S&P 500 Index, employing approximately 4,000 people worldwide. The company sells numerous branded and generic products around the world. In total, Cephalon sells more than 150 products in nearly 100 countries. More information on Cephalon and its products is available at http://www.cephalon.com/

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