mesoblast
the regenerative medicine company

asx announcement

PHASE 3 MEETING SCHEDULED WITH FDA FOLLOWING POSITIVE RESULTS OF BONE MARROW REGENERATION TRIAL

Melbourne, Australia; 12 July 2010: Australian regenerative medicine company, Mesoblast Limited (ASX:MSB; ADR:MBLTY), today announced that based on positive results from its bone marrow transplant clinical trial, conducted at the University of Texas MD Anderson Cancer Center, a formal meeting has been scheduled with the United States Food and Drug Administration (FDA) to discuss a proposed Phase 3 clinical trial program.

For this Phase 3 program, the patented allogeneic, or "off-the-shelf", Mesenchymal Precursor Cells (MPCs) will be used under a US FDA Orphan Drug Designation to expand haematopoietic stem and progenitor cell numbers in patients with haematologic malignancies.

Mesoblast's objective is to develop a therapy that results in effective bone marrow reconstitution without the potentially life-threatening complication of graft-versus-host disease that occurs in as many as 60 per cent of patients who receive bone marrow transplants from unrelated adult donors.

In the first 25 patients transplanted with MPC-expanded haematopoietic progenitors from cord blood, 80 per cent successfully achieved the key composite endpoint at 100 days of survival with sustained engraftment of both neutrophils and platelets. This is significantly higher than the rate of 38 per cent for this composite endpoint achieved after transplantation with non-expanded cord blood in the United States registry of 300 patients collected by the Center for International Blood and Marrow Transplant Research. To date, only four patients (16 per cent) receiving expanded cord blood have developed severe graft-versus-host disease.

"By increasing the overall success rate of an allogeneic bone marrow transplant while reducing the risk of graft-versus-host disease, our platform technology has the potential to lower the risk of infections, bleeding, and death in critically ill patients with haematologic malignancies following chemotherapy," said Mesoblast Chief Executive Professor Silviu Itescu.

"Our upcoming discussions with the FDA, based on the positive results from this trial, will enable us to provide a clear timetable to product commercialisation and early revenues," added Professor Itescu.

About Orphan Drug Designation
Orphan drug designation is reserved for therapies which are being developed for conditions affecting up to 200,000 patients annually in the United States, and allows for an accelerated review process by the FDA, seven-year market exclusivity in the United States upon obtaining marketing authorisation, tax benefits, and exemption from user fees.

About Mesoblast Limited
Mesoblast Limited (ASX:MSB; ADR:MBLTY) 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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