MESOBLAST ON TRACK FOR PHASE 3 BONE MARROW TRANSPLANT TRIAL FOLLOWING POSITIVE MEETING WITH FDA

Melbourne, Australia; 16 August 2010: Australian regenerative medicine company, Mesoblast Limited (ASX:MSB; ADR:MBLTY), today provided market guidance on its Phase 3 bone marrow transplant program following a formal meeting with the United States Food and Drug Administration (FDA).

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

In the meeting with the FDA, Mesoblast proposed a Phase 3 clinical trial whose design, size, duration, and primary endpoints were based on results from the 25 patient pilot trial performed at the University of Texas MD Anderson Cancer Center. Comparable control data were obtained from both MD Anderson Cancer Center and a United States registry of 300 patients collected by the Center for International Blood and Marrow Transplant Research.

The meeting was very constructive, with the FDA providing the company with expected guidance on Phase 3 primary endpoints and duration of patient follow-up. As a result of the positive meeting, and to ensure full alignment on product approval requirements, Mesoblast will seek to obtain from the FDA a binding Special Protocol Assessment (SPA) prior to commencing the Phase 3 trial. The SPA provides an agreement between the FDA and the Company regarding the design, including size and clinical endpoints, of the pivotal trial to support an efficacy claim in a Biologic License Application (BLA).

Today less than 30 per cent of individuals who could use an unrelated donor bone marrow transplant actually receive one because for the rest a fully matched donor cannot be found. Perfect matching is required because of the high risk of the potentially life-threatening complication of severe graft-versus-host disease (GVHD).

Mesoblast's objective is to make available a source of unrelated donor bone marrow cells which can be used without full matching to effect rapid bone marrow reconstitution with a low risk of GVHD. The Company believes that this would expand the use of bone marrow transplantation to all those in need of the procedure but who currently cannot find a donor.

Based on this meeting with the FDA, and in line with previous guidance, Mesoblast remains on track to file an Investigational New Drug (IND) submission to the FDA to commence a Phase 3 trial for its bone marrow transplant product by the end of this year. Mesoblast has sufficient cash reserves to fund the Phase 3 trial.

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.

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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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