



## asx announcement

### **SUCCESSFUL BONE MARROW REGENERATION IN CANCER PATIENTS USING CORD BLOOD EXPANDED BY PROPRIETARY STEM CELLS**

**Accelerated registration strategy, earlier product revenues expected**

- **"Off-the-shelf" proprietary stem cells expand umbilical cord blood by 40-fold**
- **Transplantation of expanded cord blood results in safe, successful, and rapid bone marrow regeneration**
- **Potential of therapy to reduce infection, bleeding, and death**
- **Major unmet medical need expected to facilitate accelerated product registration**

**Melbourne, Australia; 6 November 2009:** Australian regenerative medicine company, Mesoblast Limited (ASX:MSB), today announced successful results from the first 18 patients receiving a bone marrow transplant using umbilical cord blood expanded by the patented allogeneic, or "off-the-shelf", Mesenchymal Precursor Cells (MPCs).

Mesoblast's United States-based associate company Angioblast Systems Inc. is conducting the trial at the University of Texas M. D. Anderson Cancer Center, Department of Stem Cell Transplantation and Cellular Therapy. The US National Institutes of Health (NIH) has funded treatment in up to 30 patients.

Executive Director Professor Silviu Itescu told institutional investors attending the UBS Healthcare Conference in Sydney today that the Company's objective is to develop a therapy that results in bone marrow reconstitution as effectively as unrelated adult bone marrow, but without the potentially life-threatening complication of graft-versus-host disease which occurs in as many as 60% of patients.

Professor Itescu said the proprietary MPCs expanded haematopoietic stem cells in umbilical cord blood by approximately 40-fold. In patients receiving MPC-expanded cord blood, the median time to neutrophil recovery was 16 days and to platelet recovery 38 days, compared with approximately 30 days and over 90 days, respectively, in published reports of patients transplanted with an unexpanded cord. To date, only two patients have developed Grade III/IV graft-versus-host disease, compared with approximately 40% in published reports of patients transplanted with unexpanded cord blood.

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

The MPC product used in this trial is being developed under a US Food and Drug Administration (FDA) orphan drug designation granted to Angioblast for expanding haematopoietic stem and progenitor cell numbers in patients with haematologic malignancies.

In view of the important nature of the unmet medical need, Angioblast will seek to accelerate product registration in the US, Europe and Australia.

"This product has the potential to significantly shorten our timetable to commercialisation and early revenues," added Professor Itescu.



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### **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 US, and allows for an accelerated review process by the FDA, seven-year market exclusivity in the US upon obtaining marketing authorisation, tax benefits, and exemption from user fees.

### **About Mesoblast Limited**

Mesoblast Limited (ASX:MSB) is committed to the development of novel treatments for orthopaedic conditions, including 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 developed over more than 10 years relating to the identification, extraction and culture of adult Mesenchymal Precursor Cells (MPCs). The Company has acquired 38.4% of Angioblast Systems Inc., an American company developing the platform MPC technology for the treatment of cardiac, vascular and eye 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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