mesoblast
the regenerative medicine company

asx announcement

FIRST PATIENTS IN BONE MARROW TRANSPLANT TRIAL SHOW EARLIER ENGRAFTMENT

Potential for accelerated Phase 3 program

- First five bone marrow transplant patients safely implanted
- Earlier engraftment seen compared with standard therapy
- Potential for accelerated Phase 3 program
- Orphan drug designation for "off-the-shelf" product may translate to earlier revenues

Melbourne, Australia; 24 June 2009: Australian regenerative medicine company Mesoblast Limited today announced successful results from the first five patients who underwent bone marrow transplantation with haematopoietic stem and progenitor cells expanded by the patented allogeneic, or “off-the-shelf”, Mesenchymal Precursor Cells (MPCs).

The Phase I/II trial in up to 30 patients is being conducted by Mesoblast’s US-based associated company Angioblast Systems Inc. at the University of Texas M. D. Anderson Cancer Center, Department of Stem Cell Transplantation and Cellular Therapy. The trial is funded through a grant awarded by the United States National Institutes of Health (NIH).

Successful bone marrow reconstitution and engraftment was achieved in all five patients with haematologic malignancies who received MPC-expanded haematopoietic stem and progenitor cells from cord blood, with no cell-related adverse events. The median time to engraftment was 15 days, approximately two weeks faster than expected without MPC expansion.

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

Executive Director Professor Silviu Itescu said these initial results achieved with the Angioblast allogeneic MPCs were extremely encouraging.

“By significantly reducing the time to engraftment and increasing the overall success rate of an allogeneic bone marrow transplant, this technology has the potential to lower the risk of infections, bleeding, and death in critically ill patients with haematologic malignancies following chemotherapy,” he said.

In view of the important nature of the unmet medical need, the Company will seek to obtain US FDA clearance to commence an accelerated Phase 3 program if subsequent patients in the trial continue to show enhanced bone marrow engraftment potential.

“This would represent a significantly shortened timetable to product commercialisation”, 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 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; PINK:MBLTY) 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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