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FDA GRANTS ORPHAN DRUG DESIGNATION FOR USE OF PROPRIETARY STEM CELLS IN BONE MARROW TRANSPLANTS

Opportunity for accelerated product commercialisation and market exclusivity

Key Points

- Bone marrow transplants represent new market opportunity
- Orphan drug designation allows for quicker product registration
- Fast-track program may translate to earlier revenues
- FDA to guide on size, timing and scope of registration trial

Melbourne, Australia; 17 September 2008: Australia's regenerative medicine company, Mesoblast Limited (ASX: MSB; USOTC: MBLTY), today announced that the United States Food and Drug Administration (FDA) has granted an orphan drug designation for the use of the patented adult stem cell technology in patients undergoing bone marrow transplantation.

The FDA awarded Mesoblast's US-based sister company, Angioblast Systems Inc., the right to use the proprietary "off-the-shelf" allogeneic mesenchymal precursor cells for insufficient haematopoietic stem cell production in patients with hematologic malignancies who have failed treatment with conventional chemotherapy.

According to the March issue of *Biology and Bone Marrow Transplantation*, the probability that an individual in the United States will require a haematopoietic stem cell bone marrow transplant sometime during their life is 1 in 217. The FDA's orphan drug designation is reserved for new drugs or therapies being developed to treat diseases or conditions affecting less than 200,000 patients annually in the United States. Orphan drug designation 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.

Hematopoietic stem cells are used to regenerate bone marrow in patients whose own bone marrow is damaged and destroyed by treatments for various cancers. The greater the number of haematopoietic stem cells transplanted, the greater the likelihood that the bone marrow transplant will successfully engraft and regenerate a patient's damaged bone marrow.

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In preclinical studies, the patented allogeneic mesenchymal precursor cells have been shown to significantly expand the number of haematopoietic stem cells in culture. The results of these studies formed the basis for the successful orphan drug submission to the FDA.

Mesoblast's Executive Director, Professor Silviu Itescu, said the orphan drug designation was a significant milestone for the platform stem cell technology.

"It broadens the potential commercial applications to conditions requiring repair and regeneration of bone marrow, including various cancers and genetic diseases," he said.

"Significantly, orphan drug designation for our cells in these conditions may facilitate earlier revenues and market exclusivity," Professor Itescu added.

About Mesoblast

Mesoblast Limited (ASX:MSB; USOTC: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 that have been developed over more than 10 years and which relate to the identification, extraction and culture of adult Mesenchymal Precursor Cells (MPCs). The Company has also acquired 39% of Angioblast Systems Inc., an American company developing the platform MPC technology for the treatment of cardiovascular 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.

For further information, please contact:

Julie Meldrum
Corporate Communications Director
Mesoblast Limited
T: + 61 (03) 9639 6036
M: +61 (0) 419 228 128
E: julie.meldrum@mesoblast.com
W: www.mesoblast.com