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NON-HEALING BONES REPAIRED IN CLINICAL TRIAL USING ADULT STEM CELLS

Results support international multi-centre program for product commercialisation

Melbourne, Australia; 6 August 2008: The Royal Melbourne Hospital and Australia's regenerative medicine company, Mesoblast Limited, today jointly announced successful results from the long bone fracture repair clinical trial using Mesoblast's proprietary adult stem cell technology.

Ten patients with a total of 11 non-healing fractures of the long bones in the legs (following road trauma in 8) were operated on using Mesoblast's proprietary stem cells. After completing 12 months of follow-up, eight achieved complete bony union post stem cell implantation, and a ninth (with fractures of both the femur and tibia) achieved bony union of the tibia only, within a median time of 4 months. These same patients had a non-united fracture for up to 41 months prior to cell implantation, with a median of 10 months.

Of the 8 patients who had successful long bone union, all have been able to fully weight bear and resume daily activities. In these patients, Mesoblast's technology eliminated the need for a second operation to harvest bone from the pelvis. Equally as important, no adverse events related to the stem cell therapy occurred during this period. The remaining two patients had complex road trauma fractures involving multiple bones, which required re-operation.

Principal Investigator and orthopaedic surgeon, Mr Richard de Steiger, said the results were "exciting and underscore the extremely bright future for this cutting-edge technology.

"The positive outcomes in this trial pave the way for randomised, multi-centre clinical trials using Mesoblast's allogeneic or unrelated donor cells.

"Good results are likely to be seen with allogeneic cells as there should be reproducibility of outcomes and enhanced dosage predictability using a batched product derived from a young, healthy donor," Mr de Steiger said.

Mesoblast's Executive Director, Professor Silviu Itescu, said that Mesoblast's current focus is on Phase 2 Investigational New Drug (IND) submissions to the United States Food and Drug Administration (FDA) for the company's allogeneic stem cells in the treatment of non-union and high-risk fresh fractures.

"These results clearly show that our proprietary stem cell technology is safe and effective for speeding up bone fracture repair. There is a clear need for a minimally invasive, highly effective therapy to accelerate fracture repair and treat or prevent non-union, and we believe that Mesoblast's technology is ideally suited to deliver such a product," Professor Itescu said.



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Tens of millions of people worldwide suffer from non-union long bone fractures, a debilitating condition mainly associated with victims of road accident trauma and which, in some cases, may result in limb amputation. Many more patients suffer from severe fractures that heal slowly or poorly and are at high risk for non-union. These conditions represent major costs to health authorities globally and major commercial opportunities for Mesoblast.

About The Royal Melbourne Hospital

The Royal Melbourne Hospital is one of Victoria's leading public teaching hospitals and adult trauma centre, providing acute tertiary referral services at its City Campus and aged care, rehabilitation, ambulatory care and residential and community services at its Royal Park Campus.

About Mesoblast

Mesoblast Limited (ASX:MSB;USOTC:MBLTY) is committed to 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 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.

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