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MESOBLAST TO APPLY FOR REGULATORY APPROVAL OF ITS BONE FRACTURE REPAIR PRODUCTS

Earlier Revenues Anticipated Through Distribution to Australian Hospitals and Clinicians

Melbourne, Australia: 23 July 2009; Australian regenerative medicine company, Mesoblast Limited (ASX:MSB), today announced that it had commenced a formal process aimed at obtaining licenses from the Therapeutic Goods Administration (TGA) to commercially manufacture and distribute its adult stem cell products in Australia.

Mesoblast will seek to obtain TGA regulatory approval of its proprietary cell manufacturing process that will be provided and managed under a contractual agreement with a current TGA-licensed cell manufacturer, Cell Therapies Pty Ltd.

Mesoblast Executive Director, Professor Silviu Itescu, said TGA approval of its first product would result in earlier revenues by making a fracture repair product available to hospitals and clinicians throughout Australia.

Recently, Mesoblast successfully completed an Australian clinical trial of its proprietary autologous stem cell therapy for the repair of non-healing long bone fractures of the legs. The bone repair product for this trial was manufactured by Cell Therapies.

Non-healing long bone fractures affect millions of people worldwide, are usually a complication of road accident trauma, are very debilitating, and in some cases result in limb amputation.

“We are excited at the prospect of making our bone repair product available for those patients who have poorly-healing fractures of their long bones and for whom no satisfactory alternatives are available,” Professor Itescu said.

The Managing Director of Cell Therapies, Mr Ray Wood, said that entering into this contractual agreement was in large part driven by Mesoblast’s excellent clinical and manufacturing achievements to date, which he fully expects will meet the high standards of quality assurance and patient safety required by the TGA.

Professor Itescu added: “Australian regulatory approval will enable us to formulate a template that could be duplicated in other jurisdictions on a country by country basis,” he said.



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About Mesoblast

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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