mesoblast
the regenerative medicine company

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MESOBLAST'S MARKET EXCLUSIVITY FOR ITS BIOLOGIC PRODUCTS STRENGTHENED BY NEW UNITED STATES HEALTH CARE ACT

- Key provision in new United States Patient Protection and Affordable Care Act provides a biologic innovator such as Mesoblast with 12 years of exclusive market protection from date of biologic product approval
- Modifying the structure of the biologic product to improve safety, purity, or potency may result in further 12 years of market exclusivity
- As biologic innovators, Mesoblast and its United States-associate company Angioblast Systems, are well positioned to significantly extend the period of United States commercial exclusivity for their cell therapy products well beyond initial patent expiration dates
- This materially increases long-term revenue projections for both companies

Melbourne, Australia; 6 April 2010: Australian regenerative medicine company and biologic innovator, Mesoblast Limited (ASX:MSB; ADR:MBLTY), today provided an assessment on how the recently enacted United States Patient Protection and Affordable Care Act (HB 3590) is expected to have a positive impact on the commercial prospects for both Mesoblast and its United States-associated company, Angioblast Systems Inc.

The assessment indicates that the Act will facilitate a material increase in the long-term revenue projections for both companies for their biologic products in the United States, the world's largest market for regenerative medicines.

Of particular relevance to both companies is a key provision in the Act, which provides a biologic innovator with long-term exclusive market protection of its approved product against abbreviated approval of biosimilar biologic products by the United States Food and Drug Administration (FDA). A biosimilar product is deemed to be interchangeable with an already approved reference biologic based upon highly similar analytical studies, and clinical trials that demonstrate safety, purity and potency for the same indication.

The Act explicitly prohibits FDA approval of a biosimilar until 12 years after the date on which the reference biologic product is first approved. It further stipulates an additional 6 months of exclusivity for the use of reference biologic products in the paediatric population.

In addition, under the Act the innovator may receive a further 12 years of exclusivity from the date of approval of any subsequent biologic product which has a structure that has been modified to result in a change in safety, purity, or potency of the reference biologic.

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Maintaining commercial exclusivity for its biologic products through a robust international patent portfolio is fundamental to Mesoblast's commercial strategies. The United States Patent and Trademark Office has already granted Mesoblast and Angioblast key composition-of-matter and manufacturing patents for their innovative cell therapy products. These patents provide exclusive commercial protection for the companies' reference biologic products in the United States through to at least 2019, with potential for significant patent life extension. Additional patents have been filed covering specific uses of the companies' biologic products that considerably extend the duration of patent protection.

The new provisions for biosimilar biological products within the Patient Protection and Health Care Affordability Act, which was signed into law 23 March 2010, now provides both Mesoblast and Angioblast with the potential to significantly extend commercial exclusivity for their cell therapy products in the United States well beyond initial patent expiration dates. This will serve to significantly increase long-term revenue projections for both companies, and to facilitate their strategic business partnerships.

About Mesoblast
Mesoblast Limited (ASX:MSB;ADR: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. www.mesoblast.com

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