mesoblast
the regenerative medicine company

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Corporate Strategy Key to Mesoblast's Success

Chief Executive's Message to Annual General Meeting

Melbourne, Australia; 24 November 2011: Mesoblast Chief Executive, Professor Silviu Itescu, today provided shareholders at Mesoblast's Annual General Meeting with an overview of the company's corporate strategy and major highlights of recent achievements.

Professor Itescu said that the key to Mesoblast having emerged as the world's leading regenerative medicine company lies in the ability of its leadership team to understand and manage corporate risk and to build upon a substantial foundation of knowledge. This has been successfully achieved by having

(a) developed a cutting-edge, proprietary Mesenchymal Precursor Cell (MPC) platform technology which delivers a broad product pipeline, and increases the likelihood of multiple successful product outcomes,
(b) ensured a strong cash position signaling independence during challenging financial times and enabling simultaneous development of multiple new products, and
(c) executed world-class strategic partnerships to ensure global distribution strength (Teva/Cephalon) and best-in-breed manufacturing capability (Lonza).

A major highlight of the year was the successful completion of Mesoblast's Phase 2 clinical trial in congestive heart failure, and the presentation of the results to the American Heart Association by the independent principal investigator of the study.

Professor Itescu said: "The study successfully met its stated primary endpoint of product safety and feasibility, with no cell-related adverse events at any of the doses tested. As important, the study successfully met the only endpoints that the United States Food and Drug Administration (FDA) considers to be acceptable for approval of a product in a Phase 3 trial for congestive heart failure, namely reduction in cardiac mortality and heart failure hospitalizations.

Professor Itescu referred shareholders to the US FDA Guidance for Industry, Cellular Therapy for Cardiac Disease, October 2010, which states that: *'In general, Phase 3 studies should use endpoints such as mortality and cardiovascular or heart failure hospitalizations, whereas endpoints, such as ejection fraction, that have not been validated as surrogates for clinical outcome are not considered to be acceptable as primary efficacy endpoints for pivotal trials'.*

"The American Heart Association presentation showed that over a 22-month mean period of follow-up, patients treated with our cardiovascular MPC product Revascor™ had a significantly lower cardiac mortality than controls (2% vs 20%, p=0.02). The risk of Major Adverse Cardiac Events (MACE), a composite which incorporates cardiac mortality, heart attacks and vascular events, was reduced by 78% in patients treated with all doses of Revascor™ (p=0.011).

Most strikingly, the patient group treated with the highest dose of Revascor™ experienced no deaths, had no episodes of heart failure hospitalization over 18 months of follow-up, and demonstrated improvement in both heart volumes and in functional capacity, parameters which are known to correlate well with improvement in heart failure.

On the basis of these positive results, Mesoblast anticipates that discussions will be held shortly with the FDA regarding appropriate clinical design and commencement of Phase 3 trials for Revascor™.

Other clinical highlights accomplished this year included:

- The expansion of the cardiovascular franchise to include a Phase 2 trial for early treatment of major heart attacks to prevent heart failure
- The expansion of the spinal franchise from cervical and lumbar spinal fusion to include a Phase 2 trial to treat degenerative disc diseases
- Commencement of a Phase 3 trial in bone marrow transplantation
- Commencement of a Phase 2 trial for wet age-related macular degeneration, and
- Achieving promising preclinical results for Type 2 diabetes – the first trial using Mesoblast's intravenous product.

Professor Itescu highlighted the results obtained by Mesoblast in a non-human primate study of Type 2 Diabetes: "The results of the study showed that a single intravenous injection of Mesoblast's proprietary allogeneic, or off-the-shelf MPCs, could significantly reduce fasting blood glucose levels over at least a two month period in a dose-dependent manner. In addition to the glucose-lowering effects of the MPCs, there was a direct correlation between reductions in fasting blood glucose levels over time and reductions in C-reactive protein (C-RP), an established major predictor of heart attacks and death in patients with Type 2 Diabetes. Together, these results suggest that MPC therapy may reduce blood glucose and at the same time be cardioprotective in Type 2 diabetic patients."

Mesoblast expects to commence a randomized, placebo-controlled Phase 2 trial in Type 2 Diabetes early in 2012 comparing the effects over a 12-week period of a single intravenous injection of one of three escalating doses of allogeneic MPCs with placebo in poorly-controlled patients with Type 2 Diabetes. This represents the first of a number of new major indications Mesoblast will target with its intravenous product formulation, including lung diseases, immunologic conditions, and osteoporosis.

Professor Itescu said that 2012 would see Mesoblast continue to generate strong newsflow as the company executes on further strategic objectives, and accelerates commercialization of its adult stem cell products through Phase 2 and Phase 3 clinical trial programs.

"With $256 million in cash reserves, we are very well funded. In addition, our strategic partnership with Teva will facilitate execution of late-stage clinical trials as well as ensure global distribution strength on subsequent product regulatory approvals," he added.

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About Mesoblast
Mesoblast Limited (ASX:MSB) is a world leader in commercialising biologic products for the broad field of regenerative medicine. Mesoblast has the worldwide exclusive rights for a series of patents and technologies developed over more than 10 years relating to the identification, extraction, culture and uses of adult Mesenchymal Precursor Cells (MPCs). www.mesoblast.com

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