asx announcement



FDA Agreement on Mesoblast's Use of Singapore Manufacturing Facility for Clinical Trial Production of Proprietary Mesenchymal Precursor Cells

New Facility Will Support Product Delineation Strategies, Increase Geographical Reach, and Reduce Risk of Single Site Reliance

Melbourne, Australia, 13 February 2013: Mesoblast Limited (ASX: MSB; OTC ADR: MBLTY) today announced that United States Food and Drug Administration (FDA) is in agreement for Mesoblast to supply its proprietary Mesenchymal Precursor Cells (MPCs) for clinical trials in the United States under Investigational New Drug (IND) protocols, from Lonza's contract manufacturing facility in Singapore, in addition to its United States facility.

This follows the successful transfer of Mesoblast's MPC manufacturing process from the United States to the Singapore facilities of its contract manufacturer Lonza. As the clinical indications pursued under IND by Mesoblast continue to broaden, particularly using intravenous delivery of MPCs for diseases of excessive inflammation and immunity, the Singapore facility will serve to support strategies for new product delineation.

As previously announced, the FDA has agreed that Mesoblast's manufacturing process is acceptable for Phase 3 clinical supplies. Mesoblast plans to use product manufactured in the Singapore plant in global Phase 3 trials.

Mesoblast Chief Executive Professor Silviu Itescu said: "Having multiple geographic sites to manufacture our MPC products to FDA compliance is an integral part of Mesoblast's corporate strategy for product delineation, and offsets risks of single site dependence.

"We anticipate that our operations in Singapore, where we maintain exclusive access to Lonza's manufacturing facilities for allogeneic cells, will expand in line with our growth in global capacity requirements for product supply, new product lines, and partnering strategies."

Mesoblast Limited

Mesoblast Limited is a world leader in the development of biologic products for the broad field of regenerative medicine. Mesoblast's patented Mesenchymal Precursor Cell (MPC) technology is being developed for an extensive range of major clinical diseases, including inflammatory and immunologic conditions, diabetes and its complications, orthopedic spine conditions, and cardiovascular disorders. www.mesoblast.com

For further information, please contact:

Julie Meldrum Global Head of Corporate Communications T: + 61 3 9639 6036

E: julie.meldrum@mesoblast.com