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FDA agrees to Mesoblast MPC supply in the US

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Singapore:Ã?Â Mesoblast announced that US FDA is in agreement for the supply of its proprietary Mesenchymal Precursor Cells (MPCs) for clinical trials in the US under Investigational New Drug (IND) protocols, from Lonza's contract manufacturing facility in Singapore, in addition to its US facility.

This follows the successful transfer of Mesoblast's MPC manufacturing process from the US to the Singapore facilities of its contract manufacturer Lonza. As the clinical indicationsÃ?Â pursued under IND by Mesoblast continue to broaden, particularly using intravenous delivery ofÃ?Â 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 isÃ?Â acceptable for phase III clinical supplies. Mesoblast plans to use product manufactured in theÃ?Â Singapore plant in global phase III trials.

Mesoblast CEO Professor Silviu Itescu, said that, "Having multiple geographic sites toÃ?Â manufacture our MPC products to FDA compliance is an integral part of Mesoblast's corporateÃ?Â strategy for product delineation, and offsets risks of single site dependence."Ã?Â

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