mesoblast
the regenerative medicine company

asx announcement

Mesoblast Reaches Key Manufacturing Agreement with FDA for Supply of Mesenchymal Precursor Cells in Phase 3 Clinical Trials

Melbourne, Australia, 20 November 2012: Mesoblast Limited (ASX: MSB; OTC ADR: MBLTY) today announced that it has reached agreement with the United States Food and Drug Administration (FDA) on the manufacturing process to supply its proprietary mesenchymal precursor cells (MPC) for Phase 3 clinical trials. In addition, it has established with the FDA a clear pathway for commercial manufacturing supply of its cell therapy products.

The FDA agreed:

- that Mesoblast's extensive characterization and testing of its MPC technology platform was acceptable and consistent with manufacturing expectations for Phase 3 clinical supplies
- with Mesoblast's proposed assays to demonstrate potency for its MPC product, a key requirement for entry into Phase 3 clinical trials
- with the scope of product comparability studies needed to support manufacturing optimizations and scale up as clinical and commercial supply demands increase.

The agreement was based on acceptance by the FDA of comparability data from Mesoblast's initial set of manufacturing runs for clinical product to be used in the upcoming Phase 3 trial for congestive heart failure.

The agreement with the FDA on Mesoblast's manufacturing process applies to supply of MPCs in Phase 3 trials for additional indications.

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

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