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mesoblast
the regenerative medicine company

# MESOBLAST PHASE 3 PROGRAM FOR DEGENERATIVE DISC DISEASE TO INCLUDE EUROPEAN SITES AFTER POSITIVE MEETING WITH EUROPEAN MEDICINES AGENCY

**New York, USA, and Melbourne, Australia; 8 April 2015:** Mesoblast Limited (ASX: MSB, USOTC: MBLTY) today announced that following positive feedback from its recent meeting with the European Medicines Agency (EMA), it intends to expand the Phase 3 clinical program of its product candidate MPC-06-ID in the treatment of chronic low back pain due to degenerative disc disease to include sites in the European Union (EU).

Mesoblast's Phase 3 program for this product candidate is currently enrolling patients in the United States under an Investigational New Drug (IND) application filed with the US Food and Drug Administration (FDA). Having received general agreement from EMA on the target patient population, trial size, primary composite endpoint, and comparators in the control population, the Company now intends to additionally enroll patients across multiple European sites.

The discussions with EMA occurred as part of combined scientific and reimbursement advice under an EU pilot program known as Shaping European Early Dialogues (SEED). The SEED pilot program was established to facilitate early dialogue between EMA, European Health Technology Assessment (HTA) reimbursement bodies, and selected companies with late-stage clinical development programs. Mesoblast's product candidate MPC-06-ID is one of only seven medicines accepted for the SEED program.

Mesoblast and SEED representatives discussed key clinical trial aspects of the development of MPC-06-ID including the safety database, mechanisms of action, patient population and trial size, composite endpoints, and comparators. The discussions also focused on access to EU markets and pharmacoeconomic endpoints that may lead to reimbursement.

The guidance from the meeting with SEED representatives may result in a final comprehensive EU development and commercialization program that has an increased likelihood of producing data that will be acceptable for both registration and reimbursement review in multiple European countries.

**Mesoblast Limited**
Mesoblast Limited (ASX: MSB; USOTC: MBLTY) is a global leader in regenerative medicine. The Company has leveraged its proprietary technology platform, which is based on specialized cells known as mesenchymal lineage adult stem cells, to establish a broad portfolio of late stage product candidates. Mesoblast's allogeneic or 'off-the-shelf' cell product candidates target significantly advanced stages of diseases where there are highly unmet medical needs, including cardiovascular conditions, orthopedic disorders, immunologic/inflammatory disorders and oncology/hematology conditions. The lead therapeutic product candidates under investigation include MPC-150-IM for chronic congestive heart failure, in partnership with Teva Pharmaceutical Industries Ltd., MPC-06-ID for chronic discogenic low back pain, MSC-100-IV for acute graft versus host disease, and MPC-300-IV for biologic refractory rheumatoid arthritis and diabetic nephropathy.

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