asx announcement

mesoblast
the regenerative medicine company

FDA CLEARS COMMENCEMENT OF PHASE 3 CHRONIC HEART FAILURE TRIAL USING MESOBLAST'S PROPRIETARY CELLS

Melbourne, Australia; 31 October 2013: Regenerative medicine company Mesoblast Limited (ASX:MSB; USOTC:MBLTY) today announced that the United States Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) filing made by Mesoblast's development and commercial partner Teva Pharmaceutical Industries Ltd to commence a Phase 3 trial in patients with chronic congestive heart failure using Mesoblast's proprietary Mesenchymal Precursor Cells (MPCs). The IND was cleared by the FDA within the minimum 30-day period following submission, and patient recruitment is expected to begin shortly.

The multi-center trial, which will be conducted by Teva, is planned to enrol approximately 1,700 patients and includes two interim analyses of efficacy and/or safety. The clinical protocol was designed after initial consultation with both the FDA and the European Medicines Agency.

The Phase 3 trial design is a double-blinded, 1:1 randomized, placebo-controlled study evaluating a single dose of 150 million MPCs delivered via transendocardial injection catheter to the left ventricle of heart failure patients with New York Heart Association (NYHA) class II or III disease and an ejection fraction ≤ 40%. The primary efficacy endpoint of the trial is a time-to-first event analysis of heart failure-related Major Adverse Cardiac Events (HF-MACE), defined as a composite of cardiac related death or resuscitated cardiac death, or non-fatal decompensated heart failure events. These non-fatal decompensated heart failure events require use of intravenous diuretics or aquapheresis during an in-hospital stay or during an outpatient visit. Adjudication of HF-MACE will be performed by an independent, blinded clinical endpoint committee.

The MPC dose for the Phase 3 trial was chosen on the basis of results from a 60-patient Phase 2 trial which has shown that heart failure patients treated with the 150 million MPC dose have not experienced any HF-MACE over the three-year follow-up period compared with an HF-MACE incidence of approximately 30 per cent for the control group over the same period.

Mesoblast Chief Executive Silviu Itescu said: "We believe that Mesoblast's proprietary mesenchymal lineage cells have the potential to offer long-term beneficial outcomes to the millions of patients suffering from heart failure worldwide.

"Importantly, in 2014 we plan to have products in active Phase 3 clinical trials in all four of our core major therapeutic areas of focus: cardiovascular medicine (congestive heart failure), inflammatory/immune diseases (Crohn's disease), orthopedics (spinal fusion and intervertebral disc repair) and oncology (acute Graft versus Host Disease, and cord blood expansion in bone marrow transplantation)," Itescu said.

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Congestive Heart Failure

Congestive heart failure (CHF) is a leading cause of hospitalization in the industrialized world. According to the American Heart Association, about six million people in the United States have been diagnosed with CHF, with an additional 670,000 new cases currently diagnosed each year.

About Mesoblast

Mesoblast Limited (ASX:MSB;USOTC:MBLTY) is a world leader in the development of biologic products for the broad field of regenerative medicine. The Company's proprietary technologies include its Mesenchymal Precursor Cell and culture-expanded Mesenchymal Stem Cell technology platforms, Dental Pulp Stem Cells and expanded Hematopoietic Stem Cells. Mesoblast's allogeneic or 'off-the-shelf' regenerative medicine products are being developed for the treatment of conditions with significant unmet medical needs. The lead product candidates use its mesenchymal lineage cells in four major and distinct areas - systemic inflammatory conditions, cardiovascular diseases, orthopedic diseases of the spine and oncology conditions. www.mesoblast.com

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