mesoblast
the regenerative medicine company

asx announcement

Positive Outcome from FDA Meeting for Type 2 Diabetes Clinical Program Using Intravenous Delivery of Mesoblast's Proprietary Adult Stem Cells

Melbourne, Australia; 22 November 2011: Global regenerative medicine company, Mesoblast Limited (ASX: MSB), today announced that it has reached agreement with the United States Food and Drug Administration (FDA) on the key elements of the company's first clinical trial using intravenous delivery of its proprietary allogeneic, or off-the-shelf, mesenchymal precursor cell (MPC) technology in patients with Type 2 Diabetes. Based on the positive outcome of the FDA meeting held on November 18, Mesoblast will file an Investigational New Drug (IND) submission within the next 30-60 days to seek clearance for patient recruitment.

The randomized, placebo-controlled Phase 2 trial will compare the effects of a single intravenous injection of one of three escalating doses of allogeneic MPCs with placebo in poorly-controlled patients with Type 2 Diabetes. The primary safety endpoint of the study will be at 12 weeks, and during this period patients will be evaluated for effectiveness of the treatment in terms of blood glucose control and changes in various hormones that may be abnormal in patients with Type 2 Diabetes. In addition, the trial will monitor treatment-related changes in C-reactive protein (C-RP), an established major predictor of heart attacks and death in patients with Type 2 Diabetes.

The MPC doses which will be tested as a single injection in the clinical trial will be 0.3, 1 and 2 million MPC/kg, identical to the doses Mesoblast has already shown to cause a dose-dependent reduction in blood glucose levels over an 8-week period in 17 non-human primates with hyperglycemia, obesity and Type 2 Diabetes. In addition to the glucose-lowering effects of the MPCs, there was a direct correlation between reductions in fasting blood glucose levels over time and reductions in C-RP, suggesting that MPC therapy may be cardioprotective in Type 2 diabetic patients.

The FDA and Mesoblast also reached agreement to extend an ongoing non-human primate study concurrent with the IND submission in order to assess the durability of glucose-lowering effects following a single intravenous MPC injection, and to evaluate the safety and effectiveness of repeat MPC dose therapy.

Type 2 diabetes accounts for 90-95 per cent of the 230 million people with diabetes in the industrialized world, with its prevalence increasing at an alarming rate. In the United States alone, according to data from the Centers for Disease Control and Prevention (CDC) there were 25.8 million people of all ages with diabetes in the United States in 2010 (8.3% of the United States population), of which 18.8 million people were diagnosed and 7 million were undiagnosed (Source: National Diabetes Fact Sheet, 2011). With a growth rate of 2.6% per year, this number is expected to increase to more than 35 million in 2020.

About Mesoblast
Mesoblast Limited (ASX:MSB) is a world leader in commercialising biologic products for the broad field of regenerative medicine. Mesoblast has the worldwide exclusive rights for a series of patents and technologies developed over more than 10 years relating to the identification, extraction, culture and uses of adult Mesenchymal Precursor Cells (MPCs). www.mesoblast.com

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